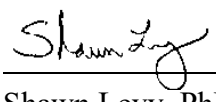
Exhibit 6

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION ***THIS DOCUMENT RELATES TO ALL CASES***	**MDL NO. 16-2738 (MAS) (RLS)**

SECOND AMENDED RULE 26 EXPERT REPORT OF SHAWN LEVY, PHD

Dated: May 28, 2024



Shawn Levy, PhD

The following amended report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. My opinions are as follows:

I. Qualifications and Background

I am the Chief Scientific Officer at Element Biosciences and formerly the Chief Scientific Officer of Discovery Life Sciences. In my current role, I focus on developing disruptive DNA sequencing technology on the AVITI platform. My work is centered around applications, methodology, and product strategy for use in research and the commercial market, as well as research partnerships and collaboration with academia, industry, and commercial entities. This work includes performance assessment for DNA sequencing and developing techniques for testing and diagnosing patients with undiagnosed and rare diseases. I also have ongoing topical research with collaborations in various areas such as changes in immune cell gene expression with environmental changes, genetic risk and sex differences in brain disorders, use of AI in genome interpretation, transcriptome changes in COVID-19 patients, alternative splicing in betacoronaviruses, and transcriptome analyses during immune surveillance and cell proliferation.

I was the founding director of the Genomic Services Laboratory and a faculty investigator at the HudsonAlpha Institute for Biotechnology. I previously served as executive director of the HudsonAlpha Clinical Services Laboratory, LLC, which I launched in 2014. I am adjunct faculty in the Department of Genetics and Department of Epidemiology at the University of Alabama at Birmingham, adjunct faculty in the Department of Biological Sciences at the University of Alabama at Huntsville. Prior to joining the faculty at HudsonAlpha, I was a faculty member in the Department of Molecular Physiology and Biophysics and the Department of Biomedical Informatics at Vanderbilt University Medical Center from 2000 until 2009. I began at the rank of Research Assistant Professor and advanced to Assistant Professor prior to joining HudsonAlpha in 2009. I continued my appointment at Vanderbilt as an Adjunct Associate Professor of Biomedical Informatics after joining HudsonAlpha's faculty.

My academic positions were continuously funded, primarily from the NIH, for nearly 20 years. My extramural funding support has been in excess of $100M and I have been a principal investigator in programs such as the Gabriella Miller Kids First Program and the All of Us

Research Program. I have been an author or co-author on over 200 peer-reviewed publications that have over 55,000 citations. I serve as an ad hoc reviewer for scientific journals, including Nature, Nature Genetics, Science, Cell, Genome Research, and several others. I have been a co-chair of the Genomics Working Group of the American Medical Informatics Association, a community of scientists and healthcare professionals that work to facilitate collaboration and share knowledge across a continuum, from basic and applied research to the consumer and public health arenas.

I received my Ph.D. in biochemistry and completed a postdoctoral fellowship in genetics at Emory University in Atlanta, where I set up a microarray facility at the Emory Center for Molecular Medicine. My education, training, and experience are further set forth in my Curriculum Vitae (CV), attached to this report as **Exhibit A**.

As detailed in my CV, my research activities have examined several fundamental questions in human cancer, such as the role of viral infection in head and neck cancer, the role of genetic mutation in risk for secondary cancer events following initial treatment, the genetics of B-cell lymphoma, hepatosplenic T-cell lymphoma and malignant melanoma, and the role of STAT3 in triple-negative breast cancer. As the founding and Executive Director of the HudsonAlpha Clinical Services Laboratory, I engaged in research interests and responsibilities in the clinical use of genetic testing for cancer risk and treatment stratification. HudsonAlpha launched the Information is Power campaign and provided genetic testing for breast and ovarian cancer risk to women across Alabama free of charge. My lab at HudsonAlpha supported the Alabama Genomics Health Initiative, which tests for genetic risks and carrier status for several diseases, including breast and ovarian cancer. This body of work in basic and clinical research, in combination with earlier epidemiological work in the Shanghai Women's Health study, provides the experience, education, and expertise to develop this report.

I have been retained to describe the role of genetics in the pathogenesis of cancer in general and specifically ovarian cancer. I have been asked to assess whether perineal use of talcum powder products induces a biologically plausible mechanism or mechanisms that result in ovarian cancer. Lastly, I have been asked to evaluate the genetic testing results of six individual plaintiffs and to opine on the impact, if any, the results had on their development of ovarian cancer.

My report consists of a review of existing works and materials from various sources, including primary literature, review articles, and other cited sources, and my conclusions regarding

this cause-and-effect relationship. My opinions are based on assessing and weighing the totality of the evidence, including relevant literature and available documentation, and my experience as a geneticist and scientific researcher. The methodology I have used to reach my opinions in this case is generally accepted in the scientific community and is the same methodology I use in my research and other professional activities.

My opinions below are held to a reasonable degree of scientific certainty. My opinions reflect my sole and independent judgment at the time of this report.

A list of the materials I have considered is attached to this report as **Exhibit B**. My billing rate is $500 per hour. I have not testified by deposition or at trial during the last four years.

II. Cancer Overview

Cancer has become a descriptor that is ubiquitously used but describes an extraordinarily complex and diverse collection of medical conditions. Cancer is also a word representing an amazingly complicated and often misunderstood collection of diseases. Cancer is a disease of unregulated cell growth at the most basic level. Cancer's simplicities end with that brief description. From conception until death, humans experience an unending cycle of cell growth, differentiation, and death. As infants grow to children and then to adults, there is an array of growth processes that occur that represent the milestones of development and maturation, many of which continue throughout adulthood. These processes are an orchestra of highly coordinated and regulated events with essential checks and balances. When those highly regulated processes are defective or the checks and balances malfunction, the growth of the cells can become unregulated. Which tissue or cells become unregulated, and precisely what process is impacted defines the type of cancer and its progression. Some cancer types can be aggressive and highly metastatic when unregulated cells invade other body parts and destroy organs and tissues. Other types of cancer remain restricted to specific organs or cell types and may be less aggressive.

The DNA within our cells provides the genetic code or instructions to create the cells, tissues, and organs that make humans. Subtle changes in that code lead to the diversity of people worldwide, while more substantial changes in that code create the diversity of life forms around us, from the smallest bacteria to the largest plants and animals. All cells have one set of instructions that provides the information for cells to divide, tissues to grow, and how cells should die.

III. The Role of Gene Mutations in the Development of Cancer

Cancer is a general term used to describe conditions of unregulated cell growth that disrupt normal cellular and organ processes. Changes in cell growth lead to a wide variety of disease phenotypes that make up the diversity of cancers. Cancers are typically dictated by the tissue origin of the unregulated growth and the extent of metastasis to other tissues or organs. Cancer is a disease caused by DNA changes (mutations) that disrupt normal cell growth and regulation. Our DNA is organized into thousands of individual genes, each containing a specific subset of instructions telling the cell what functions to perform and how to grow and divide. Mutations that cause cancer most commonly disrupt the regulation of the cell cycle (i.e., stages of cell growth and division). The following classifications of mutations are commonly found in cancer, but many other gene mutations can also contribute.

Increasing cell growth and division. A gene mutation can initiate rapid cell growth and division, resulting in many new cells with the same mutation. Proto-oncogenes are a group of genes that regulate cell growth, differentiation, division, and death. When a proto-oncogene is mutated, it can become an oncogene that then instructs the cell to grow rapidly in an unregulated manner.

Loss of growth inhibition. A gene mutation can result in the renewed growth of a previously quiescent cell. Normal cells regulate their division so that the human body contains the appropriate number of each cell type. When the tumor suppressor genes that provide this inhibitory control become mutated, cells become cancer cells and continue to grow and amass. An example of one such gene is *TP53*, which is discussed in more detail below.

Loss of DNA repair. Gene mutations can also affect the genes that proofread DNA and fix mutations before they can have a detrimental effect. DNA repair genes detect errors in cellular DNA and correct them. A mutation in a DNA repair gene may mean that other errors aren't corrected, leading cells to become cancerous through unchecked replication of damaged cells. Examples of DNA repair genes include *BRCA1* and *BRCA2*, which are discussed in more detail below.

Gene mutations can be classified by when they occur.

1) Inherited gene mutations: Inherited gene mutations are those mutations an individual is born with and is present in all body cells. These types of mutations define traits and characteristics that have a family history. This type of mutation directly accounts for a small percentage of cancers. The indirect effects of this type of mutation are an area of active research. A growing number of genes and mutations are known to increase the risk of cancer. Specific mutations in *BRCA1* and *BRCA2* increase the risk for breast and ovarian cancer by disrupting DNA repair, for example. While additional gene mutations associated with cancer are being identified, the percentage of individuals affected by those mutations will be significantly less than those affected by *BRCA1* and *BRCA2*.

2) Acquired (somatic) gene mutations: Somatic mutations are acquired after birth. Most gene mutations that directly cause cancer occur after birth and aren't inherited. Several events or exposures can cause gene mutations. These include environmental exposures such as smoking, radiation, and cancer-causing chemicals (carcinogens). Biological and lifestyle exposures such as viruses, hormones, and chronic inflammation are also known to result in cancer-causing mutations. Each exposure type has its own mechanism for increasing the risk of cancer. These mechanisms may be direct, such as radiation directly damaging DNA or asbestos causing mesothelioma, or indirect, such as an external agent causing a cellular reaction or inflammatory response that leads to DNA damage or mutation.

Both inherited and acquired gene mutations work together to cause cancer. While genetic testing has become commonplace for assessing risk for cancer and directing treatment, the catalog of oncogenes, tumor suppressor genes, and DNA repair genes make genetic testing valuable and impactful for informing patients of their genetic risk for cancer. Genetic testing generally detects inherited mutations. Genetic screening does not detect acquired gene mutations because they occur only in specific cells. Inheriting a genetic mutation that increases risk to cancer doesn't guarantee that cancer will occur. One or more additional mutations may be needed to initiate or cause cancer, and the inherited mutation could increase the chance of metastasis or disease progression. The inherited gene mutation could increase susceptibility to cancer when someone is exposed to a specific cancer-causing substance. For example, chemical and other environmental agents, such as talcum powder products, can cause mutations that, acting along with inherited mutations, cause

ovarian cancer. Conversely, individuals may still develop cancer if they do not have mutations known to predispose them to cancer.

In summary, cancer does not begin and progress in a straightforward manner. Instead, it occurs on a spectrum. Transitioning from normal to metastatic disease is not a simple on/off switch. It involves numerous steps, pauses, and evolutions that vary between individuals and cancer types.

IV. The Role of Genetics in Ovarian Cancer

Ovarian cancer is the primary cause of death from gynecologic disease and the second most common gynecologic malignancy in the United States.[1] Since the pathogenesis, treatment, and clinical courses are similar, the term "ovarian cancer" often includes ovarian epithelial cancer, fallopian tube cancer, and peritoneal cancers. Researchers now believe most of these cancers originate in the distal portion of the fallopian tube (Levanon, Crum and Drapkin 2008). The significant mortality is primarily associated with late diagnosis and resistance to therapy (Bowtell 2010). Epithelial ovarian cancer (EOC) includes most malignant ovarian neoplasms (Chan, Cheung et al. 2006) that can be classified based on morphologic and molecular genetic features into the following types: serous (OSC; low and high grade), endometrioid (EC), clear cell (OCCC) and mucinous (MC) carcinomas.

Certain specific genetic and transcriptional signatures are associated with each histological subtype. Low-grade OSC cases generally have genetic alterations in *BRAF*, *KRAS*, *NRAS*, and Erb-B2 Receptor Tyrosine Kinase 2 (*ERBB2*); high-grade OSC has mutations in Tumor Protein P53 (*TP53*), *BRCA1/2*, Neurofibromin 1 (*NF1*), RB Transcriptional Corepressor 1 (*RB1*), and Cyclin-Dependent Kinase 12 (*CDK12*) (Chan, Cheung et al. 2006). Homologous recombination repair of DNA damage is defective in approximately 50% of high-grade serous cancers along with alterations in signaling pathways such as PI3, Ras, Notch, and FoxM1 (Nunes and Serpa 2018).

Endometroid carcinoma (EC) subtypes are associated with mutations in AT-Rich Interaction Domain 1A (*ARID1A*), Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha (*PI3KCA*), Phosphatase and Tensin Homolog (*PTEN*), Protein Phosphatase 2

[1] https://www.cdc.gov/cancer/ovarian/statistics/index.htm

Scaffold Subunit Alpha (*PPP2R1α*), and mismatch repair deficiency. Ovarian clear cell carcinoma (OCCC) subtypes have been found with de novo expression of *HNF1β* (Mabuchi, Kawase et al. 2009, Shen, Fridley et al. 2013) as well as inherited mutations in *ARID1A*, *PI3KCA*, *PTEN*, Catenin Beta 1 (*CTNNB1*) and *PPP2R1α*. MC comprises tumors associated with inherited mutations in *KRAS* and a high frequency of *ERBB2* amplification with overexpression of mucin-coding genes (Banerjee and Kaye 2013, Jayson, Kohn et al. 2014).

In addition to inherited mutations, environmental exposure can result in DNA changes or acquired gene mutations that lead to cancer. These sources can be from exposure to minerals such as asbestos, talc, or nickel, chemical exposures such as benzene or formaldehyde, and natural radiation sources like radon or ultraviolet light. These exposures constantly damage human DNA. Fortunately, cells have robust DNA repair mechanisms to ensure DNA damage is repaired before the DNA is replicated. These "proofreading" mechanisms react to DNA damage and stop DNA replication. The mechanisms involve checkpoint control proteins such as the p53 protein, which halts the cell cycle if DNA is damaged, thus suppressing tumor production. Cells that do not express functional p53 protein exhibit high mutation rates in response to DNA damage, accelerating the formation of tumors.

BRCA1 and BRCA2 proteins also function in the DNA repair pathway. *BRCA1* and *BRCA2* are expressed in breast and other tissue cells and help repair damaged DNA, or destroy cells if DNA cannot be repaired. They are involved in the repair of chromosomal damage resulting from double-strand breaks. BRCA1 functions as part of a protein complex called BRCA1-associated genome surveillance complex (BASC). BASC combines with several other proteins to form a large complex that senses DNA damage. BRCA2 is a complex protein that, among other things, interacts with the RAD51 protein, creating a complex vital for DNA repair (Andreassen, Seo et al. 2021).

Individuals can inherit *BRCA1*, *BRCA2*, or *TP53*[2] mutations and are termed "positive" for the gene mutation. Such mutations will detrimentally affect the ability to repair DNA or sense the presence of damaged DNA. These defects allow additional mutations to accumulate in cells, leading to a higher probability of cells becoming cancerous. *BRCA1*, *BRCA2*, and *TP53* mutations

[2] Genes consist of genetic information that code for functional proteins. Both the gene and the protein they code share the same alphanumeric name. To avoid confusion, genes are italicized in text and proteins are not. For example: *BRCA1* (gene) and BRCA1 (protein).

can also be acquired in specific cells. If those cells form a tumor, the cancerous tissue can be tested for these gene mutations.

BRCA mutations are inherited in an autosomal dominant fashion, meaning inheriting only one copy (a monoallelic, or heterozygous mutation) results in increased cancer risk. Some individuals with a heterozygous mutation in the *BRCA1* or *BRCA2* gene will develop cancer during their lifetime, but others will not. Penetrance refers to the proportion of individuals with a genetic mutation who exhibit symptoms of the disorder. Where some carriers do not develop a disorder, as in the case of *BRCA* carriers, the condition is said to have incomplete penetrance. In such instances, additional genetic, environmental, and lifestyle factors must be present for the disorder to manifest. The lifetime risk for ovarian cancer is approximately 40 percent for *BRCA1* carriers and 15 to 20 percent for *BRCA2* carriers (Berek, Crum and Friedlander 2012, Paluch-Shimon, Cardoso et al. 2016). Therefore, the presence of mutations in the *BRCA* genes does not guarantee that carriers will get cancer. These mutations make a person more susceptible to developing cancer when exposed to a carcinogen (Park, 2018; Vitonis, 2011; Wu, 2015).

Mutations in *BRCA* genes are found in the minority of epithelial ovarian cancer cases, suggesting additional mechanisms involving other genes that predispose women to ovarian cancer. The location of the mutation within the *BRCA1* and *BRCA2* genes has been associated with different ovarian cancer risk (Thompson, Valdimarsdottir et al. 2002, Coppa, Buffone et al. 2014, Bayraktar, Jackson et al. 2015). Additionally, several common alleles, or alternate forms of a gene, have been found to modify ovarian cancer risk for *BRCA1* and *BRCA2* mutation carriers. These modifier genes alter how information from a gene is used to synthesize a final gene product (gene expression), which in turn causes a disease. They are hypothesized to act as low to moderate penetrance alleles contributing to ovarian cancer risk. (Ramus, Vierkant et al. 2008, Sellers, Huang et al. 2008, Barnes and Antoniou 2012, Saed, Diamond and Fletcher 2017). These modifiers consist of changes in the DNA called single-nucleotide variants (SNVs), resulting in a point mutation in the gene. If the mutation causes a change in protein amino acid, the mutation can result in a functionally or structurally altered protein. If the mutation does not change an amino acid or the amino acid change does not alter function or structure, the mutation may be benign. Some affected proteins are oxidants, antioxidants, or otherwise involved in regulatory pathways involving cancer risk, as discussed below.

Lynch syndrome is another hereditary condition that increases the risk of ovarian cancer. It is caused by mutations that impair DNA mismatch repair, and the disease is inherited in an autosomal dominant manner similar to *BRCA* mutations. As in the case of *BRCA* mutations, due to incomplete penetrance, inheriting a Lynch-associated mutation does not guarantee an individual will get cancer. Still, the risk of cancer will increase when exposed to a carcinogen.

Myriad Genetics was an early pioneer in developing commercial genetic testing for *BRCA1* and *BRCA2* mutations and predicting breast and ovarian cancer risk. As with all inherited traits, a positive family history is the strongest indicator of genetic risk alleles in an individual. Since the exact identity of those risk alleles and the magnitude of cancer risk remain unknown until testing is performed, early guidelines for testing were based on a positive family history. The availability of testing has increased, and the costs of testing have fallen. However, genetic testing remains a relatively rare practice in the general population. Since the early 1990s, advanced molecular biological technologies have allowed for the connection to be made between specific genetic mutations and the resulting hereditary cancers. The genes involved in cancer development are well established because of the large number of individuals tested and the ability to trace their genetic inheritance. The overall spectrum has additional variants and genes with minor involvement. For example, genetic testing can identify variants of unknown significance (VUS), which have insufficient or conflicting evidence associating them with a disease. More discussion of genetic testing and variants of unknown significance is included in section VII below. The implications, if any, of those variants are difficult to discern due to their rarity, and the likelihood that their action depends upon additional specific and complex interactions that occur in rare situations involving a combination of variations and dysregulation. The history of *BRCA1* and *BRCA2* testing serves as an important example of the complexities of cancer genetics and the challenges that still remain. This story is well summarized in a recent publication by Toland and colleagues from the Breast Cancer Information Core (BIC) Steering Committee (Toland, Brody and Committee 2019). The last decade of genetic analysis has revealed extensive genetic variation in cancer, making discerning highly penetrant driver mutations from variable passenger mutations a statistical analysis (Forbes, Beare et al. 2015, Wishart 2015). The fact that few genes have been identified with significant effect size indicates that it is unlikely that additional genes with effects sizes like BRCA1 and 2 have been missed in breast and ovarian cancer. Therefore, it is improbable

that any emerging variants could have a single-gene effect size like known mutations such as *BRCA1* or *BRCA2*.

V. Response to Cellular Injury

As mentioned, the human body requires continuous cell growth and development for normal everyday health and function. Some tissues and cell types continually turn over. Our skin, blood cells, immune cells, and the cells that line our digestive tract are examples of tissues or cells that are constantly growing and replacing older or damaged cells. In the case of an injury, a complex cascade of events begins, which involves inflammation and culminates in wound healing. During tissue injury, cell proliferation is enhanced while the tissue regenerates. After the healing is complete, proliferation and inflammation subside.

If proliferating cells sustain DNA damage or mutations that alter cell growth or cell regulation, those cells may continue to proliferate in certain microenvironments. Those environments are often rich in inflammatory cells and growth factors that support cell growth. Essentially, this is like a positive feedback cycle of injury and attempted regeneration and growth. Recent studies have shown a link between inflammation associated with wound healing and ovarian cancer cell seeding (Jia, Nagaoka et al. 2018). In addition to inflammation, the innate immune response plays a role in promoting cancer development and progression. These observations are generally accepted in the scientific literature (Coussens and Werb 2002, Pardoll 2002).

VI. Inflammation

A. The Role of Inflammation in Cancer - General

The functional relationship between cancer and inflammation was first described in the mid-1800s. Rudolf Virchow noted leucocytes in neoplastic tissues in 1863 and made a connection between inflammation and cancer (as cited in Balkwill and Mantovani, 2001). He noted that the "lymphoreticular infiltrate" was reflective of the cancer origin at sites of chronic inflammation. Research published over the last 20 years has provided a further understanding of the inflammatory microenvironment of malignant tissues and validates Virchow's hypothesis. Furthermore, the links between cancer and inflammation now have solid implications for prevention and treatment.

Macrophages are versatile immune-system cells that play various roles in health and well-being. They act in tissues and free-floating cells in the blood that engulf and digest cellular debris, foreign substances, infectious microbes, cancer cells, and anything that does not have the correct cell surface proteins to indicate a healthy cell to the body. They take various forms with various names throughout the body and have specialized tasks, including recruiting other immune cells like lymphocytes to sites of infection or acting as antigen-presenting cells to T cells. Upon activation by contact with substances foreign to the body, macrophages release small proteins called cytokines. Generally speaking, macrophages can increase or decrease inflammation depending on the cytokines released.

Tumor-associated macrophages (TAM) are a significant component of the infiltrate of most, if not all, tumors (Franklin and Li 2016). TAM derive from circulating monocytic precursors and are directed into the tumor by chemoattractant cytokines called chemokines. Tumor cells often prolong the survival of TAM by producing cytokines called colony-stimulating factors. When appropriately activated, TAM can kill tumor cells or elicit tissue destructive reactions on the vascular endothelium to disrupt blood supply to the tumor. However, TAM also produces growth and angiogenic factors and protease enzymes that degrade the extracellular matrix. Therefore, TAM can stimulate tumor-cell proliferation, promote angiogenesis, and favor invasion and metastasis (Mantovani, Bussolino and Dejana 1992, Mantovani, Bussolino and Introna 1997). Direct evidence for the importance of protease production by TAM, neutrophils, and mast cells during experimental carcinogenesis was reported more than 15 years ago (Coussens, Tinkle et al. 2000). Since that time, the report by Coussens has been cited nearly 300 times by other studies. This dual potential of TAM has been described in the literature as the "macrophage balance." (Mantovani, Bottazzi et al. 1992, Liu and Cao 2015).

B. The Role of Inflammation in Ovarian Cancer

Inflammation has also been shown to play a vital role in epithelial ovarian cancer. This principle is generally accepted in the scientific community and very well reviewed in the scientific literature over the last fifteen years, as the role of inflammation is typical in many types of cancer. (Pardoll 2002, Shan and Liu 2009, Mor, Yin et al. 2011, Pejovic and Nezhat 2011, Maccio and Madeddu 2012, Charbonneau, Goode et al. 2013, Kisielewski, Tolwinska et al. 2013). The literature reviews and many direct studies feature the immune system as an essential mediator of

ovarian carcinogenesis via two models for its role in ovarian cancer: 1) chronic inflammation and 2) incessant ovulation.

1) Chronic Inflammation: The chronic inflammation model of carcinogenesis proposes that chronic exposures to external or endogenous triggers of immunity (such as known carcinogens) and the persistence of immune cells cause ovarian cancer. These inflammatory triggers cause injury to surrounding epithelium, damage DNA by releasing reactive oxygen species (ROS), or produce cytokines that promote proliferation (Saed, Diamond and Fletcher 2017). One environmental exposure that induces inflammation in animal models and human lungs is talcum powder (Wehner 1994). Composed primarily of magnesium silicate (though it also contains asbestos, heavy metals, and other inflammatory agents as described below), the genital use of talcum powder has been linked to ovarian cancer risk in several studies (Ness, Grisso et al. 2000, Mills, Riordan et al. 2004, Merritt, Green et al. 2008, Wu, Pearce et al. 2009, Rosenblatt, Weiss et al. 2011, Penninkilampi and Eslick 2018).

2) Incessant Ovulation: As stated in (Charbonneau, Goode et al. 2013), incessant ovulation results in damage due to rupturing of the ovulating follicle, which traumatizes the ovarian surface, causing an immediate inflammatory response and wound repair. Repeating this process of damage and epithelial proliferation to repair the wound increases the risk of malignant transformation. Epidemiologic studies beginning nearly 50 years ago have implicated an increased number of ovulations as a risk factor for ovarian cancer (Mahdavi, Pejovic and Nezhat 2006). In contrast, decreased risk of (i.e., protection from) ovarian cancer has been associated with increased parity (Adami, Hsieh et al. 1994, Modan, Hartge et al. 2001), oral contraceptive use (Narod, Risch et al. 1998), breastfeeding (Jordan, Cushing-Haugen et al. 2012) and older age at first menses (Titus-Ernstoff, Perez et al. 2001). All of these protective factors impact the number of lifetime ovulations. One of these early studies from the late 1970s, which more recent investigations have further substantiated, found protective effects of "anovulatory time" by combining information on both increased oral contraceptive use and parity as well as age at first and last menses (Casagrande, Louie et al. 1979), supporting the theory of incessant ovulation as an underlying mechanism of carcinogenesis.

As a part of the inflammatory response, macrophages induce oxidative stress by producing reactive oxygen species (ROS) and reactive nitrogen species (RNS). Typically, oxidants and antioxidants maintain a balance wherein the amount of ROS does not overwhelm the body's and antioxidants' ability to regulate them. Free radicals such as ROS and RNS are highly reactive and adversely alter DNA, proteins, and lipids (which comprise cell membranes) to promote tumor development and progression. Many cancers arise from sites with chronic irritation, infection, or inflammation. Cancer cells persist in a pro-oxidant state with excess production and ROS generation that allows for tumor initiation, promotion, and progression.

The association between exposure to pathogens and chronic inflammation in tumor promotion and progression further supports the generally understood principle that chronic inflammation plays a crucial role in the development of ovarian cancer. Examples of inflammatory conditions associated with ovarian cancer include endometriosis and pelvic inflammatory disease. Evidence strongly suggests that endometriosis is a pelvic inflammatory condition (Agic, Xu et al. 2006), and that inflammation explains the association between endometriosis and epithelial ovarian cancer (Ness, Grisso et al. 2000). Studies have found a relationship between pelvic inflammatory disease and ovarian cancer risk (Merritt, Green et al. 2008, Lin, Tu et al. 2011). Moreover, the effect of non-steroidal anti-inflammatory drugs (NSAIDs) to reduce the risk of ovarian cancer provides additional support. The earlier studies focusing on NSAIDs were preliminary and results were somewhat inconsistent (Bonovas, Filioussi and Sitaras 2005, Merritt, Green et al. 2008). Still, a more recent pooled analysis examining 12 case-control studies found aspirin could reduce ovarian cancer risk by 20%-34% (Trabert, Ness et al. 2014). Moreover, the protective effect of aspirin is maintained even in individuals with genetic susceptibility to ovarian cancer (Hurwitz, Webb et al. 2023).

Additional studies illustrate the potential protective effects of anti-inflammatory agents, including unexpected drugs such as metformin. As reviewed in (Reid, Permuth and Sellers 2017), evidence supports a role of the anti-diabetic agent, metformin, in preventing and treating multiple cancers (Li 2011). Studies reviewed include a case-control study including 1,611 incident ovarian cancer cases performed using the UK-based General Practice Research Database (Bodmer, Becker et al. 2011). Long-term use (≥ 30 prescriptions) of metformin (and not sulfonylureas or insulin) was associated with a trend towards reduced risk with an odds ratio of 0.61. Though these results alone were not statistically significant, the observation that the anti-inflammatory agent,

metformin, appears to decrease cancer risk is evidence that inflammation is a primary mediator of ovarian cancer. (Irie, Banno et al. 2016).

Considering the well-established role of inflammation in cancer and the beneficial effects of anti-inflammatory compounds on cancer risk and progression, it is logical to examine the environmental factors that may directly lead to cancer or increased chronic inflammation and indirectly lead to cancer. The International Agency for Research on Cancer (IARC) has recognized for nearly thirty years that there is sufficient evidence to conclude human exposure to asbestos is a cause of ovarian cancer (IARC 1987, IARC 1987, IARC 2012). Not surprisingly, human studies have reported asbestos fibers in ovaries (Heller, Gordon et al. 1996, Langseth, Johansen et al. 2007). Meta-analysis supports the conclusion that exposure to asbestos increases the risk of ovarian cancer (Camargo, Stayner et al. 2011).

C. Talcum Powder Products

Numerous studies have examined the role of talcum powder use in developing ovarian cancers. A comprehensive and recent meta-analysis by Penninkilampi found an association between perineal talc use and ovarian cancer, with a more significant association after a higher number of lifetime applications (Penninkilampi and Eslick 2018). The Penninkilampi study identified 24 case–control (13,421 cases) and three cohort studies (890 cases). Observational studies involving 50 cases or more of ovarian cancer were deemed eligible for inclusion. Penninkilampi analyzed the association between ovarian cancer and any perineal talc use. Included studies reported specific types of ovarian cancer, long-term (>ten years) talc use, total lifetime applications, frequency, and use of talc while also using diaphragms or sanitary napkins.

The Penninkilampi study found a consistent association between perineal talc use and ovarian cancer. Variation in the magnitude of the effect was found when considering the study design and ovarian cancer subtype. Any perineal talc use was associated with an increased risk of ovarian cancer (OR=1.31, 95%CI 1.24-1.39). Greater than 3,600-lifetime applications (OR=1.42, 95%CI 1.25-1.61) were slightly more associated with ovarian cancer than less than 3,600 applications (OR=1.32, 95%CI 1.15- 1.50). Another meta-analysis by Taher, et al. in 2019, reviewing the same studies as Penninkilampi, found a similar increased risk of ovarian cancer with perineal use of talcum powder (Kadry Taher, Farhat et al. 2019). A more recent meta-analysis

focusing on frequent use (at least twice per week), concluded the increased risk of ovarian cancer with perineal exposure was 31-65% (Woolen, Lazar and Smith-Bindman 2022).

In addition to epidemiological evidence, an *in vitro* experiment by Buz'Zard and Lau reported an increase in ROS generation, increased cell proliferation, and neoplastic transformation (conversion into cancerous cells) in human ovarian cells treated with talcum powder (Buz'Zard and Lau 2007). They also found talcum powder treatment increased the number of reactive oxygen species produced by polymorphonuclear neutrophils, inflammatory cells whose role is to release significant quantities of reactive oxygen species in response to various harmful foreign stimuli. Additional studies have also shown the effects of talc on the immune response (Hamilton, Fox et al. 1984, National Toxicology 1993, Keskin, Teksen et al. 2009).

Some studies have suggested that a link between ovarian cancer and talcum powder product use may be influenced by several genes (Gates, Tworoger et al. 2008, Shukla, MacPherson et al. 2009). Gates and colleagues found that women with specific genetic variants in glutathione S-transferase M1 (*GSTM1*) and/or glutathione S-transferase T1 (*GSTT1*) may have a higher risk of ovarian cancer associated with talc use (Gates, Tworoger et al. 2008).

In another study, talcum powder increased mRNA levels of pro-oxidant enzymes in normal ovarian epithelial cells and ovarian cancer cell lines while decreasing the mRNA levels of antioxidant enzymes (Fletcher, Harper et al. 2019). Talcum powder exposure to normal and epithelial ovarian cancer cells resulted in an increased pro-oxidant state as evidenced by observing increased levels of CA-125, caspase-3, nitrate/nitrite, and key redox enzymes (Fletcher, Harper et al. 2019). CA-125 is significant because it is a biomarker that is elevated in patients with ovarian cancer and is currently FDA-approved for disease monitoring in patients with epithelial ovarian cancer, as well as those with BRCA mutations or in another high-risk group. Mandarino and colleagues independently published separate work showing the pro-oxidant effect of talc in a cell culture system. The same effects were not observed with titanium dioxide or airborne particulates (Mandarino, Gregory et al. 2020). In the same study Mandarino also reported an immune modulating effect of talc to exposed macrophages. Supporting observations of the immune-modulating effect of talc were made by Emi and colleagues in a separate study (Emi, Rivera et al. 2021).

Multiple epidemiological studies examining aggregate data from large cohorts of patients have consistently found an increased risk of talc use and ovarian cancer (Penninkilampi and Eslick

2018, Wentzensen and O'Brien 2021). Two independent research studies examined cohorts of women with self-reported use of talc, store-bought douches, or a combination of both (Gabriel, Vitonis et al. 2019, O'Brien, D'Aloisio et al. 2019). The two studies found a positive association between talc use with or without douching and ovarian cancer. Still, neither found an association of douching alone with the risk for ovarian cancer. A separate research study examined several pro-inflammatory stimuli to develop an inflammation-related risk score (IRRS) and determine the association of that risk score to ovarian cancer progression and survival (Brieger, Phung et al. 2022). As reported by Brieger et al., the study used pooled data from 8,147 women with invasive epithelial ovarian cancer from the Ovarian Cancer Association Consortium. Pre-diagnosis inflammatory-related exposures included alcohol use, aspirin use, other nonsteroidal anti-inflammatory drug use, body mass index, environmental tobacco smoke exposure, history of pelvic inflammatory disease, polycystic ovarian syndrome, endometriosis, menopausal hormone therapy use, physical inactivity, smoking status, and talc use. The study's results indicated a statistically significant trend of increasing risk of death per quartile of the IRRS (HR=1.09, 95% CI 1.03–1.14). The study reported that women in the upper quartile of the IRRS had a 31% higher death rate than the lowest (95% CI 1.11–1.54) (Brieger, Phung et al. 2022). Although the work by Brieger and colleagues does not determine the role of any single activity or exposure in disease progression or survival, it adds additional evidence supporting the role of inflammation in the development, progression, and survival of ovarian cancer. Inflammation from any source is potentially harmful, and when inflammation is introduced chronically to the genital region using external compounds such as talcum powder, the risk of developing ovarian cancer increases. The Brieger study demonstrates that increased inflammation is associated with poor survival in advanced ovarian cancer.

A 2024 publication by O'Brien et al reported on updated data from the Sister Study and attempted to account for various potential biases and misclassification errors that may contribute to the variance observed between the previous 2016 publication and other epidemiological studies examining genital use talc and the risk for ovarian cancer. After applying their methods to evaluate potential recall bias and to account for the role of exposure misclassification in Sister Study data, O'Brien et al concluded there is a positive association between talc use and ovarian cancer (HR range, 1.17-3.34)(O'Brien, Wentzensen et al. 2024). The greatest risk was observed in women between the ages of 20 to 39. The age results highlight a new and important risk stratification.

This was highlighted in the accompanying editorial to the O'Brien study (Harris, Davis and Terry 2024): "Given that genital powder use and douching are modifiable exposures potentially associated with a highly fatal disease, these data suggest that people at risk for ovarian cancer, particularly those in their 20s and 30s, should be made aware of the potential risks." This recent study did not attempt to define a single or specific mechanism and notes that in the conclusions. Epidemiological studies generally do not offer mechanistic conclusions so the notation in the paper and accompanying editorial are unsurprising.

D. Constituents of Talcum Powder Products - Asbestos, Fibrous Talc, Heavy Metals and Fragrance Chemicals

In addition to the platy talc, I have seen evidence that talcum powder products, including Johnson's Baby Powder and Shower to Shower, contain asbestos[3] and heavy metals[4], such as chromium, cobalt, and nickel. A 2017 study by Longo and Rigler on historic samples of Johnson & Johnson Baby Powder ranging in production date over many years showed over one-half (17 of 30) of the samples contained asbestos (Longo and Rigler 2017). Fibrous talc was found in 15 of the 30 samples. A 2018 study by Longo and Rigler reported both the presence of fibrous anthophyllite and fibrous talc in products tested from 1978 (Longo and Rigler 2018). Additionally, I have reviewed the expert report of Drs. Longo and Rigler reporting that 37 of 56 historical talcum powder samples contained amphibole asbestos and 41 of the 42 samples tested contained fibrous talc.[5] In 2019, the FDA tested Johnson's Baby Powder and found that it contained chrysotile asbestos and talc fibers.[6]

Asbestos has long been recognized as a carcinogen, and exposure can cause mesothelioma, and cancers of the lung, larynx, and ovary (IARC 1987, IARC 2012). It is established that asbestos exposure can result in macrophage activation, inflammation, generation of reactive oxygen and reactive nitrogen species, tissue injury, genotoxicity, and resistance to programmed cell death (IARC 2012). One of the direct mechanisms is through interactions between internalized fibers

[3] Ex. 28 and Ex. D-1A, Hopkins Dep. (Aug. 16 & 17, 2018; Oct. 26, 2018; and Nov. 5, 2018); Blount, 1991; Paoletti, 1984.
[4] Ex. 47, Julie Pier Dep. (Sept. 12 & 13, 2018).
[5] Amended Expert Report of William E. Longo, PhD and Mark W. Rigler, PhD (February 2, 2019) (finding that 68% of the samples tested contained amphibole asbestos and 98% contained fibrous talc or talc fibers).
[6] AMA Analytical Services, Inc. – Certificate of Analysis – Job Name: Task 3 – Analysis of Official Samples; Job Number: CLIN 1 – Task 3 (Oct. 11, 2019).

and components of mitosis, resulting in chromosomal alterations and abnormalities (Hesterberg, Butterick et al. 1986, Wang, Jaurand et al. 1987, Yegles, Saint-Etienne et al. 1993). IARC has classified asbestos as a known human carcinogen (Group 1). Human tumors resulting from asbestos exposure can be characterized by genetic and chromosomal alterations that lead to the inactivation of tumor-suppressor genes (IARC 2012).

Talc not containing asbestiform fibers has been found by IARC to be a Group 2b or "possible" carcinogen (IARC, 2010). IARC has determined that fibrous talc or talc-containing asbestiform fibers (talc occurring in a fibrous habit) is a carcinogen to humans (IARC 2012).

IARC classifies chromium and nickel as Group 1, "carcinogenic to humans" (IARC 2012). Cobalt is classified as Group 2B, "possibly carcinogenic to humans" (IARC 2006). IARC defines possibly carcinogenic as "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation has been considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence." Established mechanisms of chromium carcinogenesis include DNA damage, mutation, genomic instability, and cell transformation (Straif, Benbrahim-Tallaa et al. 2009). Similar mechanisms result from nickel exposure (IARC, 2012). Cobalt exposure has been shown to cause increased production of reactive oxygen species and other inflammatory and proliferative changes (IARC, 2006).

I also reviewed Dr. Michael Crowley's report discussing the numerous fragrance chemicals added to talcum powder products. I agree with Dr. Crowley's opinion that these chemicals contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products. The presence of these constituents as part of talcum powder products provides additional evidence of biological plausibility for talcum powder and ovarian cancer.[7]

Carcinogenesis is a complex and dynamic process that occurs due to a combination of genetic and acquired mutations in an individual along with other processes. Mutations arising from environmental sources have an additive and possibly multiplicative effect toward ultimately causing carcinogenesis (Vitonis, Titus-Ernstoff and Cramer 2011, Wu, Pearce et al. 2015, Park, Schildkraut et al. 2018). The presence of asbestos, fibrous talc, nickel, and chromium, known carcinogens, in talcum powder products further supports the conclusion that talcum powder causes chronic inflammation.

[7] Expert Report of Michael Crowley, PhD (Nov. 15, 2018).

Based on these observations and lines of evidence, it is my opinion that talcum powder causes inflammation, which initiates a biological response that includes oxidative stress, cell proliferation, inhibition of apoptosis, and genetic mutations, which result in cancer development and progression. This process explains the biologically plausible mechanism for talcum powder products causing ovarian cancer.

VII. Genetic Testing in Oncology

A. Background

The principles of genetics or how we inherit traits and features from generation to generation have been studied for hundreds of years. Major advancements in understanding the mechanisms of genetics and role that DNA plays in health and disease have advanced rapidly over the last several decades. From discovering the structure of DNA to sequencing the first human genome to now being able to routinely sequence the genome of any individual, the advancements have been revolutionary. The haploid human genome contains slightly more than three billion bases of DNA. When we inherit a single genome copy from our mother and one from our father, those two copies work together to form the diploid human genome. DNA sequence and organization are closely shared among humans with only small individual differences. The human genome project was a multinational effort completed in 2003 to generate a single reference genome that would support continued discovery in human genetics. The human reference genome has been under continuous update and improvement since 2003. Everyone has approximately three to four million variants compared to the reference genome with the exact number dependent on the ancestry and sex of the person. Those variants and differences in how the genome is organized define the genetic blueprint for each person. Our genome and unique collection of variants define how we look, our features, and the diseases we are susceptible to. Our genome along with our environment and lifestyle choices define our health and how we age and die. Although genetics contribute significantly to disease risk and progression, environment and lifestyle are also critical factors.

Advancements in technology over the last ten years have revolutionized the ability of scientists and clinicians to analyze how genetics influence health and disease. The completion of the human genome project provided the foundation of how to interpret changes in DNA sequence

and organization. Today, comprehensive genetic testing, including whole-genome sequencing is widely accessible. International efforts have sequenced over one million genomes and several million samples have been analyzed using focused testing methods such as exome sequencing or targeted panel sequencing. Exome sequencing analyzes the portion of the human genome that encodes proteins, which is only ~2% of the total genome. Targeted panel sequencing is an approach where a small collection of genes known to be involved in a disease are analyzed. Exome and targeted panels have the advantage of being lower cost and easier to interpret compared to genome sequencing.

The collective knowledge from analyzing millions of samples has resulted in comprehensive resources for interpreting genetic testing results. When a genetic test is performed, the test results are compared to the reference genome. Variants from the reference genome are identified and annotated based on the collective knowledge. A consistent method and language to annotate variants has been developed. Variants directly involved in disease are identified as "Pathogenic Variants". Variants that are known to be neutral are annotated as "Benign". Genetic testing results also identify variants that have uncertain significance. These variants usually alter a protein sequence, but that alteration has not been proven to be associated with disease. These are called VUS for "variants of unknown/uncertain significance". The annotation status of a particular variant can be changed when there is sufficient evidence to support the change. VUS will commonly be advanced to either "Pathogenic" or "Likely Pathogenic" if there are multiple examples of that variant being detected with a specific disease. A VUS can also be annotated as "Benign" if the variant is frequently found in individuals with no evidence of disease.

Genetic testing is a common part of cancer treatment, and many companies offer tests of varying complexity. The range of complexity of these tests is from one gene to 600 genes. The larger panels that examine hundreds of genes are called pan-cancer tests since they analyze a collection of genes that are known or associated with cancer or cancer treatment but are not focused on a specific type of cancer. Single-gene tests such as sequencing BRCA1 and 2 are typically used when the analysis is focused on a specific type of cancer. These tests are intended to identify variants that alter treatment or prognosis based on annotations from previous studies. One of the limitations of focused testing in cancer is how to interpret VUS. The focused test is, by nature, biased to genes involved in cancer. When tests are negative for pathogenic variants, the next tier of interpretation is for VUS detected in the patient. It is standard practice to report VUS in genetic

testing results. VUS may be further considered after further analysis such as examining the conservation of the variant or how frequently the variant has been observed in the total population of results. If a variant is observed in the population at a rate higher than the disease incidence, it is extremely unlikely that it is associated with the disease.

I have reviewed the genetic testing results of six plaintiffs. Each of them underwent genetic testing as part of their cancer treatment. The tests and interpretation were performed at different times to determine if there were known mutations that would alter the treatment of their disease or provide information valuable for family counseling. Each patient was provided with reports or a summary of results. This review is based on the content of those reports. None of the six patients had mutations in BRCA1 or 2 nor did they have known, pathogenic mutations that would influence treatment or prognosis. The testing and results for each of the patients are summarized below.

B. Patient Testing Results

1) Linda Bondurant

Ms. Bondurant was diagnosed with clear cell carcinoma.[8] Testing was performed at MD Anderson where germline genetic testing identified a likely pathogenic variant of *SDHA* and a VUS in *PTCH1*.[9] Screening of *BRCA1* and *BRCA2* was negative. No other details on the testing results were provided. *SDHA* encodes a subunit of succinate dehydrogenase, a mitochondrial enzyme involved in the Krebs cycle. Mutations in *SDHA* can lead to paraganglioma-pheochromocytoma syndrome (PGL1), characterized by an increased risk of paragangliomas and pheochromocytomas. These conditions were not observed in Ms. Bondurant, who was diagnosed with clear cell ovarian carcinoma.[10] *PTCH1* is a tumor suppressor gene that plays a role in the Hedgehog signaling pathway, which is involved in cell growth and development. Mutations in *PTCH1* can lead to Gorlin syndrome, characterized by an increased risk of basal cell carcinoma, a type of skin cancer (Yang 2022). In my opinion, neither *SDHA* nor *PTCH1* have been implicated in ovarian cancer.

[8] BondurantL-MDAMR-00872; BondurantL-TCCMR-01667.
[9] BondurantL-MDAMR-01167, BondurantL-MDAMR-01168.
[10] BondurantL-MDAMR-01262, BondurantL-MDAMR-00872, BondurantL-MDAMR-01168.

2) Hillary Converse

Ms. Converse was diagnosed with clear cell ovarian cancer.[11] Testing was performed on a blood sample at Myriad Genetics and was negative for pathogenic variants in *BRCA1* and *BRCA2,*[12] including negative for three variants found in people of Ashkenazi Jewish descent.[13] Ms. Converse is of Jewish descent on both sides of her family and with a significant family history of cancer on her maternal side.[14] Additional genetic testing was performed at Yale and a detailed report was provided. The variant interpretation from the report is quoted below:

> "ATM, heterozygous variant. L2307F (MG19, chromosome 11:108196898 C>T). This variant has a frequency of 0.5%. It has not been reported as either a normal variant or a disease-causing mutation. The amino acid at the position is highly conserved, and the SIFT and Polyphen programs predict a deleterious effect of this variant. The significance of this variant should be evaluated in the clinical context. Testing additional family members. if available, may be useful in evaluating the segregation of this variant with disease in the family.".[15]

Although this variant changes a conserved amino acid, reviewing this variant in ClinVar finds the majority of annotations are benign or likely benign without a report of association with ovarian cancer.[16, 17]

A second variant was reported:

> "TGFBk2, heterozygous variant, A329T (HG19, chromosome 3:30713680 G>A). This variant has a frequency of less than 1/10,000. It has been reported as causing Loeys Dietz syndrome, but also was seen in an unaffected member of a Loeys Diet Family, suggesting that it does not cause Loeys Diet syndrome (Looys (2006) NEngl J Med 355, 788). A different amino acid change in this gene at position 315 was reported in a single family with Lynch syndrome. This result has not been replicated in additional families. The amino acid at position 329 is not well conserved, and SIFT and Polyphen predict no deleterious effect. This variant is unlikely to be related to the patient's phenotype."[18]

In my opinion, there is no evidence that either of these variants is pathogenic or has any association with an increased risk of ovarian cancer. These same two variants were found in Ms. Converse's mother who developed breast cancer at age 46. The report notes that the precise role

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[11] CONVERSE_HILARY_YALE_NEWHAVENHEALTH_000296.
[12] CONVERSE_HILARY_YALENEWHAVENHOSPITAL_01217.
[13] CONVERSE_HILARY_YALENEWHAVENHOSPITAL_01215.
[14] CONVERSE_HILARY_YALENEWHAVENHOSPITAL_01212.
[15] CONVERSE_HILARY_PROHEALTHPHYSICIANSOFHAMDEN_00297.
[16] https://www.ncbi.nlm.nih.gov/clinvar/variation/127430/
[17] CONVERSEH-FINEE-00075.
[18] CONVERSE_HILARY_PROHEALTHPHYSICIANSOFHAMDEN_00297.

of these variants in cancer is not fully established but recommends Ms. Converse continue screening for breast cancer.[19]

3) Anna Gallardo

Ms. Gallardo was diagnosed with endometrioid ovarian cancer.[20] Testing was done on 11 genes through GeneDx Laboratory and no mutations were found.[21] Due to these results, no additional testing was recommended for Ms. Gallardo or her relatives, as the screening she received "rules out the genes most commonly associated with hereditary risk for ovarian cancer."[22]

4) Carter Judkins

Ms. Judkins was diagnosed with high grade serous ovarian cancer.[23] Testing was performed on a blood sample at Ambry Genetics, wherein a variant of unknown significance was found in *PTEN (c.-1283G>A)*.[24] The OvaNext test analyzed 25 genes associated with hereditary ovarian cancer. The report stated "No known clinically actionable alterations were detected."[25] The patient also underwent tumor testing at Myriad Genetics. The Myriad results were negative for *BRCA1* and *BRCA2* and positive for genomic instability in the tumor. Genomic instability is a prognostic marker of the tumor and may indicate a rapidly growing tumor or one that has multiple genetic changes. Genomic instability is observed in many cancers. Mutations in *PTEN* are associated with an increased risk of breast, endometrial, and thyroid cancer. *PTEN* is a tumor suppressor gene that plays a role in cell growth and apoptosis. There are over 1,000 variants in *PTEN* that have been annotated as pathogenic or likely pathogenic and 1,180 VUS. While the genetic testing report indicates that *PTEN* mutations in general are associated with susceptibility to ovarian cancer,[26] the specific mutation identified in Ms. Judkins has not been previously reported and in my opinion, there is no evidence to define it as a pathogenic variant or that there is any association with increased risk of ovarian cancer.

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[19] CONVERSE_HILARY_YALENEWHAVENHOSPITAL_01213.
[20] GALLARDO_A_BARNES_JEWISH_HOSP_000273; GALLARDO_ANNA_WASHU_MED-00324.
[21] GALLARDO_A_GENEDX_000034 - GALLARDO_A_GENEDX_000036; GALLARDO_A_GENEDX_000123 - GALLARDO_A_GENEDX_000124.
[22] GALLARDO_A_WASHU_000170.
[23] JUDKINSC_DHMC__C_MDR000085.
[24] JUDKINSC_REC000003.
[25] JUDKINSC_REC000003.
[26] JUDKINSC_REC000004.

5) Tamara Newsome

Ms. Newsome was diagnosed with endometrioid adenocarcinoma of the ovary.[27] Blood sample testing was performed at Myriad Genetics using the MyRisk test and provided results on 25 genes. A single variant was reported as a VUS. *MUTYH c.1513T>G* (p.Cys505Gly).[28] *MUTYH* is a gene that encodes a protein involved in DNA repair. Mutations in *MUTYH* have been associated with a small increased risk of colorectal cancer, and monoallelic carriers reportedly have an increased risk for colorectal, liver, gastric and endometrial cancers, with conflicting findings with respect to breast cancer (Rodriguez-Rojas, Candelo et al. 2023). The region of *MUTYH* where the mutation is located is poorly conserved and adjacent sites are reported to be frequently mutated.[29] In my opinion, there is no evidence that this variant is pathogenic, nor that there is any association with an increased risk of ovarian cancer.

6) Pasqualina Rausa

Ms. Rausa was diagnosed with high grade serous carcinoma.[30] Testing was performed on a blood sample from Ms. Rausa with the Comprehensive Common Cancer test from GenPath. The test provides results on 46 genes with known involvement in cancer generally; it is not targeted toward ovarian cancer. One mutation was reported as a VUS in fumarate hydratase (*FH c.986A>G*).[31] Mutations in *FH* can lead to hereditary leiomyomatosis and renal cell cancer (HLRCC), characterized by an increased risk of renal cell carcinoma. The genetic testing report points out that the specific mutation was found in at least one case of head and neck paraganglioma, but does not associate it with ovarian cancer.[32] The report further points out the "variant is not located in a known functional domain," indicating the mutation does not affect a site responsible for a function or interaction.[33] In my opinion, there is no additional evidence that this VUS is pathogenic or has an association with increased risk of ovarian cancer.

[27] NEWSOMET_HCH_MDR000036.
[28] NEWSOMET_REC000003.
[29] ClinVar report: https://www.ncbi.nlm.nih.gov/clinvar/variation/238339/
[30] PRAUSAPL-000001.
[31] RausaP-GenPathMR-00005.
[32] RausaP-GenPathMR-00006.
[33] RausaP-GenPathMR-00006.

VIII. Conclusion

Based on my background, training, education, and experience as a geneticist assessing and weighing the totality of scientific and medical evidence, my opinions, which I hold to a reasonable degree of scientific certainty, may be summarized as follows:

1. Genetic mutations can be inherited or acquired. Both types are associated with cancer, including ovarian cancer.
2. Inflammation has been shown to play a vital role in epithelial ovarian cancer.
3. Talcum powder products cause chronic inflammation.
4. Talcum powder product-induced inflammation causes damage to the DNA, genetic mutation, genomic instability, and cell transformation.
5. The properties and constituents of talcum powder products act as inflammatory agents and the role of inflammation in triggering oxidative stress, activating cytokines, cell proliferation, DNA damage, and genetic mutations (such as SNVs) provide a biologically plausible mechanism for the carcinogenicity of talcum powder products.
6. Internalization of asbestiform fibers (including asbestos and fibrous talc) causes DNA damage, which provides a biologically plausible mechanism for the carcinogenicity of talcum powder products.
7. The presence of an inherited gene mutation, such as *BRCA1* or *BRCA2*, indicates a woman has an increased risk of ovarian cancer, but does not necessarily mean she will develop ovarian cancer.
8. Women with inherited gene mutations in genes involved in DNA repair, such as *BRCA1 or BRCA2*, are more as susceptible to the effect of carcinogens than women without inherited gene mutations.
9. Genetic testing is a powerful and valuable tool to guide cancer treatment, prognosis, and family planning. All patients tested were negative for highly penetrant and clinically actionable mutations in *BRCA1* and *BRCA2*.
10. In relation to the VUS noted in the six patients reviewed, there is no evidence that the variants are pathogenic with regard to ovarian cancer or have any association with an increased risk of ovarian cancer.

I reserve the right to supplement, revise, or amend this report should additional materials, including expert reports and testimony, become available. I reserve the right to review and comment on defendants' expert reports and any related testimony.

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Exhibit A

Shawn Edward Levy *Curriculum Vitae*

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Personal Statement

My research group has utilized high-performance genotyping and sequencing technologies for the past 20 years, supporting various projects from plant and animal phylogenetic studies to translational and clinical-based projects. Several publications detail our successes using various genomic technologies and in bioinformatics research. As a post-doctoral fellow at Emory University, I developed the first microarray to interrogate mitochondrial gene function. Upon joining the faculty at Vanderbilt University, I was responsible for founding and developing the Vanderbilt Microarray Shared Resource (VMSR). From 2000 to 2009, the VMSR became an internationally recognized facility supporting various genomic technologies from SNP profiling to gene expression analysis to next-generation sequencing. I joined the faculty of the HudsonAlpha Institute for Biotechnology in 2009 to develop the Genomic Services Laboratory (GSL). From 2009 through 2019, the GSL supported more than 6,000 projects from principal investigators worldwide. These projects have allowed me to collaborate and participate in various genomics projects focusing on genomic methods to decipher complex conditions. We have had a particular focus on childhood and adult cancer as well as rare disease and degenerative diseases. Our efforts have been both financially successful as well as academically successful. Our team has contributed to more than 200 peer-reviewed publications of which I am an author or co-author. More than 250 additional publications that have included data from our laboratory as a service provider have also been published since 2009. Many of these publications involve translational research or describe the genetic underpinnings of rare or complex human diseases. Although located in a non-profit institute, the GSL laboratory was developed with a focus on quality, efficiency, and innovation. Our financial and scientific successes and approach led to HudsonAlpha selling the assets of the GSL to Discovery Life Sciences in August 2019, creating a new division in the company called HudsonAlpha Discovery. The sale was the largest financial transaction in the institute's history and continues the legacy of the GSL through clinical and basic research support for academic and biopharmaceutical partners. The diversity of projects, technologies, and investigators we have worked and collaborated with over the last two decades have provided a dynamic and unique experience to evolve our own research and technology development efforts to help solve the most pressing challenges in biology. In 2022 I transitioned from Chief Scientific Officer of Discovery Life Sciences to a position at Element Biosciences. I currently serve as the Chief Scientific Officer of Element Biosciences and SVP-Applications. My responsibilities at Element Biosciences include the overall scientific strategy of the company as well as overseeing all applications development and collaborations.

Contributions to Science

The following five sections provide highlights to areas where my work has contributed to areas of science. Example publications are provided with each section and a full bibliography is provided at the end of the CV.

1. My scientific career has been a somewhat atypical in that I have spent the last 15 years focusing on the development and application of genomic and bioinformatic technologies and methods to support scientific investigation in a number of areas. While there have been substantial areas of focus, my laboratory does not operate under a single or specific biological area or hypothesis. Instead, we examine ways to improve the resolution and quality of results to answer complex questions, regardless of biological relationship. The publications below are examples of contributions to technical projects or large consortium projects with goals in the evaluation or improvement of techniques or technologies.

    a. Statnikov A, Aliferis, C, Tsamardinos, I, Hardin, D, and Levy, S. A comprehensive evaluation of multicategory classification methods for microarray gene expression cancer diagnosis. **Bioinformatics**, 2005. 21(5), p. 631-643. PMID:15374862.
    b. The MicroArray Quality Control Consortium. The MicroArray Quality Control (MAQC) project shows inter- and intraplatform reproducibility of gene expression measurements. **Nature Biotechnology**, 2006. 24(9), p. 1151-1161. PMID:16964229.
    c. The ENCODE Project Consortium. An integrated encyclopedia of DNA elements in the human genome. **Nature**. 2012. 489, 57-74. PMID: 22955616 PMCID: PMC3439153
    d. The Sequence Quality Control (SEQC) Consortium. A comprehensive assessment of RNA-seq accuracy, reproducibility and information content by the Sequence Quality Control consortium. **Nature Biotechnology**. 2014. 32 (9), 915-925. PMID:25150835; PMCID:4167418.

2. One area of early focus of my career was the development and analysis of mouse models for mitochondrial disease, including the knock out of the Adenine Nucleotide Translocase 2 (Ant2) gene leading to a more complete understanding of the permeability transition. This work also discovered methods to alter the mitochondrial DNA in stem cells and supported the first mitochondrial DNA transfers by stem cells.
    a. Levy SE, Waymire, KG, Kim, YL, MacGregor, GR, and Wallace, DC, Transfer of chloramphenicol-resistant mitochondrial DNA into the chimeric mouse. **Transgenic Research**. 1999. 8(2), p. 137-145. PMID:10481313.
    b. Sligh JE, Levy SE, Waymire KG, Allard P, Dillehay DL, Nusinowitz S, Heckenlively JR, MacGregor GR, and Wallace DC. Maternal germ-line transmission of mutant mtDNAs from embryonic stem cell-derived chimeric mice. **Proc. of the Nat. Acad. of Sciences USA.** 2000. 97(26), p. 14461-14466. PMID:11106380; PMCID:18941.
    c. Kokoszka JE, Waymire, KG, Levy, SE, Sligh, JE, Cal, JY, Jones, DP, MacGregor, GR, and Wallace, DC, The ADP/ATP translocator is not essential for the mitochondrial permeability transition pore. **Nature**, 2004. 427(6973),p. 461-465. PMID:14749836.
    d. Picard M, Zhang J, Hanecock S, Derbeneva O, Golhar R, Golik P, O'Hearn S, Levy SE, Potluri P, Lvova M, Davila A, Lin CS, Perin JC, Rappaport EF, Hakonarson H, Trounce I, Procaccio V, and Wallace DC. Progressive increase in mtDNA 3243A>G heteroplasmy results in abrupt transcriptional remodeling. **Proc. of the Nat. Acad. of Sciences USA**. 2014. 111(38), E4033-E4042. PMID:25192935; PMCID:4183335.

3. A long-standing area of research interest is the genomic analysis of cancer, both childhood

and adult. These efforts have included population-based studies and more directed research in specific cancer biology. These efforts have examined many cancer types including breast, lung, colon, and myeloid cancer.

a. Smith JJ, Deane, NG, Wu, F, Merchant, NB, Zhang, B, Jiang, A, Lu, P, Johnson, JC, Schmidt, C, Edwards, CM, Eschrich, S, Kis, C, Levy, S, Washington, MK, Heslin, MJ, Coffey, RJ, Yeatman, TJ, Shyr, Y, and Beauchamp, RD, Experimentally Derived Metastasis Gene Expression Profile Predicts Recurrence and Death in Patients With Colon Cancer. **Gastroenterology**, 2009. PMID: 19914252 PMCID: PMC3388775.

b. Powell AE, Wang Y, Li Y, Poulin EJ, Means AL, Washington MK, Higginbotham JN, Juchheim A, Prasad N, Levy SE, Guo Y, Shyr Y, Aronow BJ, Haigis KM, Franklin JL, and Coffey RJ. Lrig1, a pan-ErbB negative regulator, marks intestinal stem cells and acts as a tumor suppressor. **Cell**. 2012. 149(1), 146-158. PMID: 22464327 PMCID: PMC3563328.

c. McDaniel JM, Varley KE, Gertz J, Savic DS, Roberts BS, Bailey SK, Shevde LA, Ramaker RC, Lasseigne BN, Kirby MK, Newberry KM, Partridge EC, Jones AL, Boone B, Levy SE, Oliver PG, Sexton KC, Grizzle WE, Forero A, Buchsbaum DJ, Cooper SJ, Myers RM. Genomic regulation of invasion by STAT3 in triple negative breast cancer. **Oncotarget**. 2017;8(5):8226-38. doi: 10.18632/oncotarget.14153. PubMed PMID: 28030809; PMCID: PMC5352396.

d. McKinney M, Moffitt AB, Gaulard P, Travert M, De Leval L, Nicolae A, Raffeld M, Jaffe ES, Pittaluga S, Xi L, Heavican T, Iqbal J, Belhadj K, Delfau-Larue MH, Fataccioli V, Czader MB, Lossos IS, Chapman-Fredricks JR, Richards KL, Fedoriw Y, Ondrejka SL, Hsi ED, Low L, Weisenburger D, Chan WC, Mehta-Shah N, Horwitz S, Bernal-Mizrachi L, Flowers CR, Beaven AW, Parihar M, Baseggio L, Parrens M, Moreau A, Sujobert P, Pilichowska M, Evens AM, Chadburn A, Au-Yeung RK, Srivastava G, Choi WW, Goodlad JR, Aurer I, Basic-Kinda S, Gascoyne RD, Davis NS, Li G, Zhang J, Rajagopalan D, Reddy A, Love C, Levy S, Zhuang Y, Datta J, Dunson DB, Dave SS. The Genetic Basis of Hepatosplenic T-cell Lymphoma. **Cancer Discov**. 2017;7(4):369-79. doi: 10.1158/2159-8290.CD-16-0330. PubMed PMID: 28122867; PMCID: PMC5402251.

4. My laboratory has had the opportunity to collaborate with a number of outstanding investigators in the genetics analysis of complex neurological conditions, including autism, schizophrenia and bipolar disorders as well as ALS. We contributed significantly to the discovery of the association of de-novo rather than Mendelian mutations in these conditions, particularly in schizophrenia.

a. Xu B, Roos JL, Dexheimer P, Boone B, Plummer B, Levy S, Gogos JA, Karayiorgou M. Exome sequencing supports a de novo mutational paradigm for schizophrenia. **Nature Genetics**. 2011. 43(9), 864-868. PMID: 21822266. PMCID: PMC3196550.

b. Neale BM, Kou Y, Liu L, Ma'ayan A, Samocha KE, Sabo A, Lin CF, Stevens C, Wang LS, Makarov V, Polak P, Yoon S, Maguire J, Crawford EL, Campbell NG, Geller ET, Valladares O, Shafer C, Liu H, Zhao T, Cai G, Lihm J, Dannenfelser R, Jabado O, Peralta Z, Nagaswamy U, Reid JG, Newsham I, Wu Y, Lewis L, Han Y, Muzny D, Voight BF, Lim E, Rossin E, Kirby A, Flannick J, Fromer M, Shakir K, Fennell T, Garimella K, Boyko C, Gabriel S, dePristo M, Wimbish JR, Boone BE, Levy SE, Betancur C, Sunyaev S, Boerwinkle E, Buxbaum JD, Cook EH, Devlin B, Gibbs R, Roeder K, Schellenberg GD, Sutcliffe JS, and Daly MJ. Patterns and rates of exonic de novo mutations in autism spectrum disorders. **Nature**. 2012. 485(7397), 242-245. PMID: 22495311 PMCID:PMC3613847.

c. Xu B, Ionita-Laza I, Roos JL, Boone B, Woodrick S, Sun Y, Levy S, Gogos JA, and Karayiorgou M. De novo gene mutations highlight patterns of genetic and neural complexity

in schizophrenia. **Nature Genetics**. 2012. 44(12), 1365-1369. PMID: 23042115 PMCID: PMC3556813.

d. Cirulli, ET, Lasseigne, BN, Petrovski, S, Sapp, PC, Dion, PA, Leblond, CS, Couthouis, J, Lu, Y-F, Wang, Q, Krueger, BJ, Ren, Z, Keebler, J, Han, Y, Levy, SE, Boone, BE, Wimbish, JR, Waite, LL, Jones, AL, Carulli, JP, Day-Williams, AG, Staropoli, JF, Xin, WW, Chesi, A, Raphael, AR, McKenna-Yasek, D, Cady, J, Vianney de Jong, JMB, Kenna, KP, Smith, BN, Topp, S, Miller, J, Gkazi, A, Consortium, FS, Al-Chalabi, A, van den Berg, LH, Veldink, J, Silani, V, Ticozzi, N, Shaw, CE, Baloh, RH, Appel, S, Simpson, E, Lagier-Tourenne, C, Pulst, SM, Gibson, S, Trojanowski, JQ, Elman, L, McCluskey, L, Grossman, M, Shneider, NA, Chung, WK, Ravits, JM, Glass, JD, Sims, KB, Van Deerlin, VM, Maniatis, T, Hayes, SD, Ordureau, A, Swarup, S, Landers, J, Baas, F, Allen, AS, Bedlack, RS, Harper, JW, Gitler, AD, Rouleau, GA, Brown, R, Harms, MB, Cooper, GM, Harris, T, Myers, RM, Goldstein, DB. Exome sequencing in amyotrophic lateral sclerosis identifies risk genes and pathways. **Science**. 2015. 347(6229): p. 1436-41.

5. My laboratory has played a significant role in the discovery of the causative mutations of a number of rare but significant human diseases, particularly in the field of pediatric nephrology in collaboration with Friedhelm Hildebrandt at Harvard University. These studies applied genomic technologies to better characterize and, in some cases, diagnose or discover the causative mutation for severe phenotypes or disease.

   a. Otto EA, Hurd TW, Airik R, Chaki M, Zhou W, Stoetzel C, Patil SB, Levy S, Ghosh AK, Murga-Zamalloa CA, van Reeuwijk J, Letteboer SJF, Sang L, Giles RH, Liu Q, Coene KLM, Estrada-Cuzcano A, Collin RWJ, McLaughlin HM, Held S, Kasanuki JM, Ramaswami G, Conte J, Lopez I, Washburn J, MacDonald J, Hu, J, Yamashita Y, Maher ER, Guay-Woodford L, Neumann HPH, Obermuller H, Koenekoop RK, Bergmann C, Bei X, Lewis RA, Katsanis N, Lopes V, Williams DS, Lyons RH, Dang CV, Brito DA, Dias MB, Zhang X, Nurnberg G, Nurnberg P, Pierce E, Jackson P, Antignac C, Saunier S, Roepman R, Dollfus H, Khanna H, and Hildebrandt F. Candidate exome capture identifies mutation of SDCCAG8 as the cause of a retinal-renal ciliopathy. **Nature Genetics**, 2010. 42(10), 840-850 PMID: 20835237 PMCID: PMC2947620.

   b. Rademakers R, Baker M, Nicholson AM, Rutherford NJ, Finch N, Soto-Ortolaza A, Lash J, Wider C, Wojtas A, DeJesus-Hernandez M, Adamson J, Kouri N, Sundal C, Shuster EA, Aasly J, MacKenzie J, Roeber S, Kretzschmar HA, Boeve BF, Knopman DS, Petersen RC, Cairns NJ, Ghetti B, Spina S, Garbern J, Tselis AC, Uitti R, Das P, Van Gerpen JA, Meschia JF, Levy S, Broderick DF, Graff-Radford N, Ross OA, Miller BB, Swerdlow RH, Dickson DW, Wszolek ZK.Mutations in the colony stimulating factor 1 receptor (CSF1R) cause hereditary diffuse leukoencephalopathy with spheroids. **Nature Genetics**. 2011. 44(2), 200-205. PMID: 22197934 PMCID: PMC3267847.

   c. Fiskerstrand T, Arshad N, Haukanes BI, Tronstad RR, Pham KDC, Johansson S, Håvik B, Tønder SL, Levy SE, Brackman D, Boman H, Biswas KH, Apold J, Hovdenak N, Visweswariah SS, and Knappskog PM. Familial Diarrhea Syndrome Caused by an Activating GUCY2C Mutation. **New England Journal of Medicine**. 2012. 366(17), 1586-1595. PMID: 22436048.

   d. Carlson J, Scott LJ, Locke AE, Flickinger M, Levy S, Myers RM, Boehnke M, Kang HM, Li JZ, Zöllner S. Extremely rare variants reveal patterns of germline mutation rate heterogeneity in humans. **bioRxiv**. 2017:108290.

   e. Chao HT, Davids M, Burke E, Pappas JG, Rosenfeld JA, McCarty AJ, Davis T, Wolfe L, Toro C, Tifft C, Xia F, Stong N, Johnson TK, Warr CG, Undiagnosed Diseases N, Yamamoto S, Adams DR, Markello TC, Gahl WA, Bellen HJ, Wangler MF, Malicdan MC. A Syndromic Neurodevelopmental Disorder Caused by De Novo Variants in EBF3. **Am J**

Hum Genet. 2017;100(1):128-37. doi: 10.1016/j.ajhg.2016.11.018. PubMed PMID: 28017372; PMCID: PMC5223093.

6. The COVID pandemic presented unique opportunities to apply the genomic technologies and resources of my laboratory and collaborate with researchers from around the world to support the efforts to better understand and treat COVID and its related conditions.
   a. MacKay MJ, Hooker AC, Afshinnekoo E, Salit M, Kelly J, Feldstein JV, Haft N, Schenkel D, Nambi S, Cai Y, Zhang F, Church G, Dai J, Wang CL, **Levy S**, Huber J, Ji HP, Kriegel A, Wyllie AL, and Mason, CE. (2020) *The COVID-19 XPRIZE and the need for scalable, fast, and widespread testing.* Nat Biotechnol. 38(9): 1021-1024, doi: 10.1038/s41587-020-0655-4, PMID: 32820257, PMC: PMC7543743.
   b. Butler D, Mozsary C, Meydan C, Foox J, Rosiene J, Shaiber A, Danko D, Afshinnekoo E, MacKay M, Sedlazeck FJ, Ivanov NA, Sierra M, Pohl D, Zietz, M, Gisladottir U, Ramlall V, Sholle ET, Schenck EJ, Westover CD, Hassan C, Ryon K, Young B, Bhattacharya C, Ng DL, Granados AC, Santos YA, Servellita V, Federman S, Ruggiero P, Fungtammasan A, Chin CS, Pearson NM, Langhorst BW, Tanner NA, Kim Y, Reeves JW, Hether TD, Warren SE, Bailey M, Gawrys J, Meleshko D, Xu D, Couto-Rodriguez M, Nagy-Szakal D, Barrows J, Wells H, O'Hara NB, Rosenfeld JA, Chen Y, Steel PAD, Shemesh AJ, Xiang J, Thierry-Mieg J, Thierry-Mieg D, Iftner A, Bezdan D, Sanchez E, Campion TR, Jr., Sipley J, Cong L, Craney A, Velu P, Melnick AM, Shapira S, Hajirasouliha I, Borczuk A, Iftner T, Salvatore M, Loda M, Westblade LF, Cushing M, Wu S, **Levy S**, Chiu C, Schwartz RE, Tatonetti N, Rennert H, Imielinski M, and Mason CE. (2021) Shotgun transcriptome, spatial omics, and isothermal profiling of SARS-CoV-2 infection reveals unique host responses, viral diversification, and drug interactions. Nat Commun. 12(1): 1660, doi: 10.1038/s41467-021-21361-7, PMID: 33712587, PMC: PMC7954844.
   c. Park J, Foox J, Hether T, Danko D, Warren S, Kim Y, Reeves J, Butler DJ, Mozsary C, Rosiene J, Shaiber A, Afshinnekoo E, MacKay M, Bram Y, Chandar V, Geiger H, Craney A, Velu P, Melnick AM, Hajirasouliha I, Beheshti A, Taylor D, Saravia-Butler A, Singh U, Wurtele ES, Schisler J, Fennessey S, Corvelo A, Zody MC, Germer S, Salvatore S, **Levy S**, Wu S, Tatonetti N, Shapira S, Salvatore M, Loda M, Westblade LF, Cushing M, Rennert H, Kriegel AJ, Elemento O, Imielinski M, Borczuk AC, Meydan C, Schwartz RE, and Mason CE. (2021) Systemic Tissue and Cellular Disruption from SARS-CoV-2 Infection revealed in COVID-19 Autopsies and Spatial Omics Tissue Maps. bioRxiv. doi: 10.1101/2021.03.08/434433, PMID: 33758858, PMC: PMC7987017.
   d. Karlebach G, Aronow B, Baylin SB, Butler D, Foox J, **Levy S**, Meydan C, Mozsary C, Saravia-Butler AM, Taylor DM, Wurtele E, Mason CE, Beheshti A, and Robinson PN. (2021) Betacoronavirus-specific alternate splicing. bioRxiv. doi: 10.1101/2021.07.02.450920, PMID: 34230929, PMC: PMC8259905.

Education

College
University of New Hampshire: BS, 1994 (Biochemistry, Microbiology)
GPA 3.37
Honors Graduate, Dean's list.

Graduate School
Emory University: PhD, 2000, (Biochemistry)
GPA 3.75

Thesis title: "Genetic Alteration of the Mouse Mitochondrial Genome and Effects on Gene Expression."
Thesis advisor: Professor Douglas C. Wallace

Post-Graduate Training
Emory University, Douglas C. Wallace, March 2000-July 2000

Employment/Academic Appointments

Research Assistant Professor, Department of Molecular Physiology and Biophysics, Vanderbilt University Medical Center, Nashville, TN, July 2000-June 2003

Adjunct Faculty, Graduate training program, Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, January 2001-June 2003

Director, Vanderbilt Microarray Shared Resource, Vanderbilt University Medical Center, Nashville, TN, July 2000-August 2009

Assistant Professor, Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, July 2003-August 2009. *(Primary Appointment)*

Assistant Professor, Department of Molecular Physiology and Biophysics, Vanderbilt University Medical Center, Nashville, TN, July 2003-August 2009 *(Secondary Appointment)*

Adjunct Associate Professor, Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, August 2009-December 2017.

Adjunct Associate Professor, Department of Epidemiology, University of Alabama-Birmingham, Birmingham, AL October 2010-Present.

Adjunct Assistant Professor, Department of Genetics, University of Alabama-Birmingham, Birmingham, AL October 2010-Present.

Adjunct Associate Professor, Department of Biological Sciences, University of Alabama-Huntsville, Huntsville, AL January 2014-Present.

Director, Genomic Services Laboratory, HudsonAlpha Institute for Biotechnology, Huntsville, AL, August 2009-August 2019

Executive Director, HudsonAlpha Clinical Services Laboratory, LLC, Huntsville, AL, December 2014-August 2019

Faculty Investigator, HudsonAlpha Institute for Biotechnology, Huntsville, AL, August 2009-December 2022.

Chief Scientific Officer, HudsonAlpha Discovery, Discovery Life Sciences, Inc, Huntsville, AL, August 2019-March 2022.

Senior Vice President, Applications and Scientific Affairs, Element Biosciences, San Diego CA, February 2022-January 2023.

Chief Scientific Officer, Senior Vice President, Applications, Element Biosciences, San Diego CA, January 2023-present.

Professional Organizations

American Medical Informatics Association, Co-chair, Genomics Working Group (2006-2007)
Association of Biomedical Resource Facilities
American Association for the Advancement of Science
American Association for Cancer Research
American Society for Human Genetics

Professional Activities

Intramural-University
Vision 2020 Personalized Medicine Committee-Task Force 3 (2009)

Intramural-Departmental
Department of Biomedical Informatics Academic Progress Committee (2005-2007)
Department of Biomedical Informatics Curriculum Committee (2007-2009)

Intramural-Center Affiliations
Vanderbilt-Ingram Cancer Center, Associate Member (2000-2009)
Vanderbilt Diabetes Research and Training Center, Member (2000-2009)
Vanderbilt Digestive Disease Research Center, Member (2003-2009)
Vanderbilt Institute of Chemical Biology, Member (2004-2009)

Extramural-Journal Review
- Reviewer- Arteriosclerosis, Thrombosis and Vascular Biology (2001-present)
- Reviewer-Bioinformatics (2001-present)
- Reviewer-Journal of Biological Chemistry (2002-present)
- Reviewer-Neuropsychopharmacology (2003-present)
- Reviewer-Kidney International (2003-present)
- Reviewer-Circulation Research (2003-present)
- Reviewer-Proceedings of the National Academy of Sciences (2004-present)
- Reviewer-Mitochondrion (2004-present)
- Reviewer-Molecular Nutrition and Food Research (2005-present)
- Reviewer-Pattern Recognition Letters (2006-present)
- Reviewer-PLOS-Genetics (2006-present)
- Reviewer-Physiological Genomics (2008-present)
- Reviewer-Genome Biology (2008-present)

Extramural-Editorial
- Member, Editorial Board- Journal of the American Informatics Association (2005-2007)

Extramural-Grant Study Section
- Reviewer- Alzheimer's Association (2002-present).
- NIDDK study section ZDK1 GRB-6 "Digestive Disease Research Development Centers" December 2002.
- NIDDK study section ZDK1 GRB-6 "Digestive Disease Research Development Centers" April 2004.
- NCI study section ZCA1 SRRB-C "Innovative Technologies for the Detection of Cancer" July 2004.
- NLM special study section-P41 Biomedical Informatics Resource Grants, April 2005.
- NLM special emphasis panel ZLM1 HS RO1, July 2005

- NIH CSR shared equipment study section ZRG1 GGG-T (30, 31), November 2005.
- DOD Ovarian Cancer Review Panel OC-2, August 2006
- NIH Special Emphasis Panel ZRG1 GGG-T Genomics and Genetics Shared Instrumentation, October 2006.
- NCI study section ZCA1 SRRB-U Development of Advanced Genomic Characterization Technologies, November 2006.
- NIDDK DK-06-017 “Silvio O. Conte Digestive Diseases Research Core Centers P30”, June 2007.
- NIH Special Emphasis Panel ZRG1 GGG-A (30) - S10s genomics and proteomics shared instrumentation, July 2007.
- NIH Special Emphasis Panel ZRG1 GGG-B (30) - S10s genomics and proteomics shared instrumentation, September 2008.
- NIAAA Special Review Panel ZAA1-GG-01, November 2008
- NIH Special Emphasis Panel ZRG1 GGG-A (30) – Genes Genomes and Genetics instrumentation, October 2010.
- NIH Study Section 2011/05 GHD-Genetics of Health and Disease Study Section, February 2011.
- NIGRI Study Section 2012/05 ZHG1 HGR-P (M1) 1-H3 AFRICA Initiative, March 2012.

- ***Numerous ad-hoc reviews from 2012-2021.***

Extramural-Other Review

- Reviewer, American Association for the Advancement of Science Research Competitive Service-*Microarray Facilities for the Vermont Genetics Network*. April 2002.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Michigan Core Technology Alliance*. April 2003.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Michigan Core Technology Alliance*. April 2004.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. January 2007.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. March 2008.
- Reviewer, American Association for the Advancement of Science Research Competitive Service- *Review of Washington State Life Sciences Discovery Fund* June 2008.
- Reviewer, American Association for the Advancement of Science Research Competitive Service- *Review of Missouri Life Sciences Research Board* October 2008
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. June 2009.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. May 2010.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. September 2011.

Extramural-Advisory

- Member, Scientific Advisory Board, NuGen Technologies, Inc, San Carlos, CA, October 2003-December 2010.
- Member, Scientific Advisory Board, Genome Quebec Innovation Centre, Montreal, Quebec, 2008-2011.
- Member, Scientific Advisory Board, Rubicon Genomics, Ann Arbor, MI 2013-2017.

▪Chairman, Scientific Advisory Board, RainDance Technologies (BioRad), Billerica, MA 2015-2018
▪Member, Scientific Advisory Board, Genome Explorations Inc, Memphis, TN, 2006-2018.
▪Member, Scientific Advisory Board, Jumpcode Genomics, San Diego, CA. 2018-Present.
▪Member, Scientific Advisory Board, Covaris, Woburn, MA. 2018-Present.

Honors and Awards
▪Scholar Athlete, University of New Hampshire, 1993-1994.
▪Dean's list, University of New Hampshire, 1992-1994.
▪Career Development Award, SPORE in Gastrointestinal Cancer 2004-2005
▪Co-Chair, Genomics Working Group of the American Medical Informatics Association 2006-2007.

Teaching Activities

Graduate School Courses as Course Director
BMIF 310-Foundations of Bioinformatics and Computational Biology, 28 lectures, Spring 2004
BMIF 311-Introduction to Systems Biology, 28 lectures, Spring 2009. *This course was a newly developed course for 2009.*

Graduate School Courses as Lecturer
MPB 322-Regulation of Gene Expression, 3 lectures, Spring 2002
MPB 322-Regulation of Gene Expression, 2 lectures, Spring 2003
MPB 322-Regulation of Gene Expression, 3 lectures, Spring 2004
IGP 301-Methodology, 1 lecture, Fall 2004
IGP 301-Methodology, 1 lecture, Fall 2005
IGP 301-Methodology, 1 lecture, Fall 2006
MIM 351-Functional Genomics and Proteomics, 2 lectures, Spring 2006
BMIF 310-Foundations of Bioinformatics and Computational Biology, 7 lectures, Fall 2007
BMIF 310-Foundations of Bioinformatics and Computational Biology, 7 lectures, Fall 2008
BMIF 310-Foundations of Bioinformatics and Computational Biology, 4 lectures, Fall 2009
BMIF 310-Foundations of Bioinformatics and Computational Biology, 4 lectures, Fall 2010
BMIF 310-Foundations of Bioinformatics and Computational Biology, 1 lecture, Fall 2011

Research Supervision

Ph.D. Thesis Committee Member
Stephen VonStetina-Vanderbilt University (2001-2005)
Laura Wilding-Vanderbilt University (2003-2007)
Alex Statnikov-Vanderbilt University (2005-2008)
Alisha Russell-Vanderbilt University (2006-2010)
Mawuli Nyaku-University of Alabama-Birmingham (2010-2014)

M.S. Thesis Committee Member
Alex Statnikov (2003-2005)
Joel Parker (2000-2002)

Student Mentorship
Shristi Shrestha, PhD student (2014-2019)

Current position: Bioinformatics Scientist, Department of Stem Cell Biology, Vanderbilt University, Nashville, TN.
Nripesh Prasad, PhD student (2010-2014)
Current position: Director of Feasibility, Discovery Life Sciences, Huntsville, AL.
Sidd Pratrap MS student (2005-2007)
Current position: Director of Bioinformatics, Meharry Medical College, Nashville, TN.

Fellow Mentorship
Lewis Frey, PhD (2004-2006)
Current position: Associate Professor, Public Health Sciences, Medical College of South Carolina, Charleston, SC.

Patents Awarded

Multiplex spatial profiling of gene expression
US 7,569,392 B2

Research Support

COMPLETED

2U24HD090744-01 (Levy/Zhang)	07/01/2019 – 06/30/2022	2.40 calendar months
NIH/NICHD	$6,212,400	

Characterizing pediatric genomes through an optimized sequencing approach
Understanding the fundamental genetic changes associated with structural birth defects and childhood cancers is an important step in developing tools to allow more advanced prediction, treatment and prevention of these devastating conditions. We propose to combine the resources of two world-class centers to support researchers in their investigations of the genetics of birth defects and childhood cancers. This centralized resource will provide researchers with the tools and support necessary to advance our understanding and drive us closer to curing or preventing these diseases.
Role: Principle Investigator

1OT2OD027070-01 (Levy)	09/21/2019 - 08/31/2023	2.40 calendar months
NIH/NCATS	$6,999,491	

Population-Scale Clinical Genomics
The production of genomic data for the All of Us Research Program (AoU) is an unprecedented opportunity to support a comprehensive precision medicine effort that benefits the entire U.S. population. With the participation from patients, family members, researchers and clinicians, the AoU Research Program will impact clinical management by directing patient care, enabling pre-symptomatic genetic testing of relatives, guiding family planning measures, and triggering healthcare interventions. This proposal focuses on the production of long-read sequencing data to complement the short-read data that is being produced from DNA from participating individuals. The goal of the study is to identify structural and copy number changes detected in the long-read data that is may be missed in short-read data.
Role: Principle Investigator

5 U24 DK58749-03 (George)	09/30/2000 - 08/31/2003	1.2 calendar months
NIH/NIDDK		

Vanderbilt NIDDK Biotechnology Center
The goal of this proposal was the establishment of a Biotechnology Center for the support of genomic studies of interest to investigators funded by the NIDDK. Microarray technologies and related informatics were central to the efforts.
Role: Co-Investigator

VUMC Discovery Grant 540 (Levy) 01/01/2002 - 12/31/2003 1.2 calendar months
VUMC Internal Grant $50,000
Gene Expression Analysis of Colon Cancer
The goal of this proposal was the development of an integrated RNA and protein expression profile for colon cancer utilizing microarray and high-resolution protein profiling technologies. These profiles were useful in designing and developing both technological and informatic platforms for the combined analysis of protein and genetic profiles of cancer.
Role: Principle Investigator

ACS IRG-58-009-46 (Levy) 07/01/2003 - 06/30/2004 1.2 calendar months
ACS/VICC
Simultaneous profiling of protein and RNA expression by mass spectrometry in intact tissue sections.
The goal of this proposal is to develop a novel technology platform that facilitates the simultaneous profiling of protein and RNA species in intact tissue samples while reporting spatial position. This will provide an unprecedented resolution to examine the biology of tumor samples and host-tumor interactions.
Role: Principle Investigator

1 R21 NS043581-01A1 (McDonald) 12/01/2002 - 11/30/2004 1.2 calendar months
NIH/NINDS
Gene Discovery in a Putative Mouse Model of ADHD
In this proposal, microarray technology will be used to examine differential gene expression in the mouse model of ADHD, providing a rare opportunity to discover genes downstream of TRß activity that are able to produce all of the core symptoms and many adjunct features of ADHD.
Role: Co-Investigator

1 U01 DK063587-01 (Hayward) 09/30/2002 - 06/30/2005 1.2 calendar months
NIH/NIDDK
Genetic Markers of Transition Zone Hyperplasia
The goals of this proposal are the identification of biomarkers for prostate hyperplasia through the use of high-density microarray studies on novel models of prostate disease.
Role: Co-Investigator

W81XWH-04-1-0626 (Levy) 07/15/2004 - 07/14/2006 1.2 calendar months
Department of Defense
Simultaneous profiling of protein and RNA expression by mass spectrometry in intact breast tissue sections.
The goal of this proposal is to continue the development of a novel technology platform that facilitates the simultaneous profiling of protein and RNA species in intact tissue samples while reporting spatial position. This proposal will specifically fund the optimization of this technology for the analysis of breast tissue samples.
Role: Principle Investigator

5 P01 HL6744-04 (Hawiger) 12/01/2001 - 11/30/2006 1.2 calendar months
NIH/NHLBI
Functional Genomics of Inflammation
As part of a Program Project Grant, the goal of the Microarray Core in the Functional Genomics of Inflammation program project is to provide genome-scale expression profiling technologies to researchers involved in the program.
Role: Core Leader

1 R01 DK068261-01 (Nagy) 07/01/2004 - 06/30/2007 1.2 calendar months
NIH/NIDDK
Antipsychotic Drug-induced Weight Gain
The goal of this study is to understand the actions of antipsychotic drugs as they alter body weight. In this short subcontract with the University of Alabama, an animal model system used to study the molecular effects of selected drugs will be analyzed using genomic profiling techniques.
Role: Co-Investigator

5 P60 DK20593-27 (Powers) 07/20/2002 - 03/31/2007 1.2 calendar months
NIH/NIDDK
Diabetes Research and Training Center-Microarray and Bioinformatics Core
As part of a center grant, the goal of the Microarray Core in the Diabetes Research and Training Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in DRTC-related research.
Role: Core Leader

5 P50 CA95103-04 (Coffey) 09/24/2002 - 04/30/2007 1.2 calendar months
NIH/NCI
SPORE in GI Cancer
This study will investigate the molecular features of tumors in GI cancer and provide full support for genomic profiling projects as part of the overall SPORE program.
Role: Core Leader

5 P30 CA68485-13 (Pietenpol) 09/28/2004 - 08/31/2009 1.80 calendar months
NIH/NCI $3,553,801
Cancer Center Support Grant
As part of the Vanderbilt Ingram Cancer Center's support grant, the goal of the Microarray Core is to provide genome-scale expression profiling technologies as well as analysis and informatics support to researchers who are members of the center.
Role: Core Leader

U24 CA126563 (Myers) 09/28/2006 - 08/31/2010 1.2 calendar months
NIH/NCI
The HudsonAlpha Cancer Genome Characterization Center
We are characterizing tumors and matched non-tumor samples for copy number variations throughout the human genome as part of The Cancer Genome Atlas project, a trans-NIH initiative aimed at learning all the genetic and genomic changes associated with cancer. We use a whole-genome genotyping method to assay more than 1 million SNPs throughout the genome.
Role: Co-Investigator

1 RC1 HL100016-01 (Schey) 09/30/2009 - 09/29/2011 1.2 calendar months
NIH-ARRA Funding

Proteome and Transcriptome Markers of Hypertension in Urine and Plasma Exosomes
The goal of the proposed research is to develop a novel method for discovery of molecular markers of disease that circumvents existing obstacles. Through analysis of proteins and RNA found in lipid particles isolated from blood and urine, new markers of disease will be discovered that improve diagnosis, prognosis, and prediction of response to therapy; that is, improve personalized medicine. The new methodology will be applied to reveal biomarkers of salt-sensitivity and therapeutic response in hypertensive subjects.
Role: Co-Investigator

1 RC1 DK086594-01 (Southard-Smith) 09/30/2009 - 09/29/2011 0.60 calendar months
NIH/NIDDK $240,970
Gene Networks in Neutral Crest-derived Innervation of the Lower Urinary Tract
The studies proposed aim to identify essential genes that control development of nerves in the lower urinary tract that regulate bladder control and sexual function. These studies are important for understanding how these nerves normally develop and for deriving technologies that will restore neural function in urogenital birth defects or after pelvic surgery. This proposal is in response to the broad Challenge grant area of Regenerative medicine and meets multiple needs for basic research in development lower urinary tract innervation.
Role: Co-Investigator

5 P30DK058404-07 (Polk) 08/30/2007 - 05/31/2012 1.20 calendar months
NIH/NIDDK $727,500
Molecular and Cellular Basis of Digestive Diseases
As part of a center grant, the goal of the Microarray Core in the Vanderbilt Digestive Diseases Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in digestive disease-related research.
Role: Core Leader

5 P60 DK20593-31 (Powers) 06/01/2007 - 03/31/2012 0.24 calendar months
NIH/NIDDK $1,487,659
Diabetes Research and Training Center
As part of a center grant, the goal of the Microarray and Bioinformatics Core in the Diabetes Research and Training Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in DRTC-related research.
Role: Core Leader

P50 HG02568 (Kingsley) 4/19/2002 - 5/31/2012 1.20 calendar months
NIH/NHGRI $701,981
Center for Vertebrate Diversity
The continuation of this Center of Excellence in Genome Science (CEGS) has broad goals to understand the genetic basis for the striking biological diversity seen in vertebrate animals. We use genetics, genomics, molecular biology and computational tools to study this problem, focusing on the three-spined stickleback fish. HudsonAlpha performs many of the genomic experiments for this project, including genomic DNA sequencing, cDNA sequencing, BAC map construction, and genotyping.
Role: Co-Investigator

2 R01 CA064277-10A1 (Zheng) 08/05/2008 - 05/31/2013 0.24 calendar months
NIH/NCI $324,917
Shanghai Breast Cancer Study

This proposal is aimed at the development of novel algorithms for the analysis of high-dimensionality data towards to the discovery of causal markers and mechanisms.
Role: Co-Investigator

R01: (Myers and Boehnke) 8/30/11 - 6/30/14 2.4 calendar months
NIH $1,855,348
Whole Genome and Exome Sequencing for Bipolar Disorder
In this collaborative R01 grant, performed jointly with Dr. Michael Boehnke and colleagues at the University of Michigan, we are performing a detailed genetic analysis of bipolar disorder. We are using ultrahigh-throughput sequencing to determine the deep whole genome sequences from 1,000 individuals with bipolar disorder and 1,000 control individuals without the disorder.
Role: Co-Investigator

1 R01 AR057202 (Bridges) 4/1/2009 - 3/31/2014 0.6 calendar months
NIH/NIAMS $298,704
Genome Wide Association Study in African-Americans with Rheumatoid Arthritis
In this study, the Myers lab and Devin Absher and his lab at HudsonAlpha are collaborating with Dr. Lou Bridges and his colleagues at the School of Medicine at the University of Alabama in Birmingham to perform a genome-wide genetic association study of rheumatoid arthritis in African Americans. No budgetary or scientific overlap.
Role: Co-Investigator

US MED Research ACQ Activity (Myers) 9/16/2010 - 8/31/2015 4.0 calendar months
US Army $2,150,777
Global genomic analysis of prostate, breast and pancreatic cancer
The goals of this study are to provide an unprecedented comprehensive view of the molecular pathogenesis of prostate, breast, and pancreatic cancer, as well as the differential response to treatments in breast cancer. We will use next-generation DNA sequencing to measure mRNA, microRNA, DNA methylation, DNase hypersensitivity sites, histone modifications, and sites of transcription factor occupancy in tumors and matched non-tumor tissues for these three cancers.
Role: Co-Investigator

5 U54 HG004576-03 (Myers) 10/01/2007 - 09/30/2011 1.20 calendar months
NIH/NHGRI $3,985,643
Global Annotation of Regulatory Elements in the Human Genome
This project, which is a collaboration between the Myers group at HudsonAlpha and Barbara Wold's group at Caltech, along with contributions from Wing Wong, Arend Sidow, Serafim Batzoglou and Gavin Sherlock at Stanford, is part of the ENCODE Project, whose goals are to identify and understand the roles of all the functional elements throughout the entire human genome. Our contributions are to identify transcription factor binding sites, assess the methylation status and measure RNAs with next-gen sequencing.
Role: Co-Investigator

5UL1TR001417-02 (Kimberly) 08/18/2015 - 03/31/2019 0.60 calendar months
NIH/NCATS $83,644
UAB Center for Clinical and Translational Science (CCTS)
The UAB CCTS will enhance human health by driving scientific discovery and dialogue across the bench, bedside and community continuum. The CCTS support this overall mission in a highly integrative network of relationships. Success in creating such an environment is dependent upon success in achieving five strategic priorities: 1) enhancing research infrastructure; 2) promoting

investigator education, training and development; 3) accelerating discovery across the T1 interface; 4) expanding value-added partnerships; and 5) building sustainability.
Role: Co-Investigator

HHSN2722012000231 (Creech) 09/01/2015 - 09/30/2018 0.24 calendar months
NIH/NIAID $555,660
Influenza A/H7N9 Vaccine Administered with/without AS03 Adjuvant: Standard and Systems Biology
HudsonAlpha will receive human RNA samples from Vanderbilt University Medical Center. RNA-sequencing will be performed per specifications provided in the clinical protocol and clarified in the manual of procedures. We will perform all necessary experiments, including quality control assays. Once sequencing data are obtained, these FastQ/BAM files will be transferred to Vanderbilt University Medical Center and to the DMID Statistics and Data Coordinating Center (SDCC) for data analysis.
Role: Co-Investigator

HHSN2722012000231 (Creech) 09/01/2015 - 09/30/2018 0.24 calendar months
NIH/NIAID $56,630
Sub-study for DMID 10-0074
HudsonAlpha will receive human RNA samples from Vanderbilt University Medical Center. RNA-sequencing will be performed per specifications provided in the clinical protocol and clarified in the manual of procedures. We will perform all necessary experiments, including quality control assays. Once sequencing data are obtained, these FastQ/BAM files will be transferred to Vanderbilt University Medical Center and to the DMID Statistics and Data Coordinating Center (SDCC) for data analysis.
Role: Co-Investigator

6U19CA179514-05 (Coffey) 09/01/2013 - 08/31/2018 0.24 calendar months
NIH/NCI $39,254
Secreted RNA during CRC progression biogenesis function and clinical markers
Dr. Levy's laboratory will fully support RNA sequencing on 48-74 samples per year prepared from either total RNA or microRNA at the HudsonAlpha Institute for Biotechnology. Dr. Levy's laboratory will provide all required reagents, personnel and basic analysis support for the proposed sequencing studies during years 1-5 of the project period.
Role: Co-Investigator

5U01MH105653-03 (Boehnke) 09/19/2014 - 05/31/2018 0.60 calendar months
NIH/NIMH $23,557
Whole Genome Sequencing for Schizophrenia and Bipolar Disorder in the GPC
Dr. Levy will participate in weekly conference calls and several yearly face-to-face meetings to help make this project successful. Any new improvements in sequencing technology, data analysis and data interpretation that are developed and/or applied at HudsonAlpha will be made immediately available to this project.
Role: Co-Investigator

3P30CA013145-44S4 (Partridge) 04/01/2017 - 03/31/2018 0.60 calendar months
NIH/NCI $113,863
Comprehensive Cancer Center Core Support Grant
Dr. Myers, President and Science Director of HudsonAlpha Institute for Biotechnology, will be part of the director's council. The director's council meets on a monthly basis to advise the director on all major decisions regarding the UAB-CCC, its organization, planning and evaluation and to

approve new developmental research programs and review program leaderships. In addition, Dr. Myers will co-lead UAB-CCC's Experimental Therapeutics program. Drs. Absher and Levy will be co-leaders of the Cancer Cell Biology Program and Cancer Control & Population Sciences Program. Dr. Cooper is an Associate Scientist in Experimental Therapeutics program. They will consult investigators in study design and analysis related to genomic data.
Role: Core Leader

4UM1HG007301-04 (Cooper/Myers) 06/14/2013 - 05/31/2018 0.60 calendar months
NIH/NHGRI $1,536,927
Genomic Diagnosis in Children with Developmental Delay
The goal of this project is to address technological, analytical, and ethical challenges that prevent optimal use of DNA sequencing to improve treatment of diseases and life planning for patients and their families. We are applying next-generation DNA sequencing to meet the diagnostic needs of children with developmental delay, intellectual disability and related health problems.
Role: Co-Investigator

RFA-HG-16-011 (Cooper/Barsh/Korf) 06/01/2017 – 05/31/2021 0.60 calendar months
NIH $2,840,944
Clinical sequencing across communities in the Deep South
This proposal outlines an important study to apply WGS to diagnose neonates with rare disorders, increase participation of individuals from underrepresented racial/ethnic groups in genomics clinical trials, provide educational materials appropriate to diverse audiences, equip non-genetics healthcare providers to return WGS results, assess the impact of WGS testing and results, and engage a broad community to implement safer, more effective, and more equitably distributed genomic medicine.
Role: Co-Investigator

Publications

221 peer-reviewed publications with a total of 55,665 citations (*as of November 2023*)**.**

A full publication and patent listing can be accessed via a public Google Scholar profile at: http://scholar.google.com/citations?user=xeKJAZ0AAAAJ

NCBI Bibliography Link:
https://www.ncbi.nlm.nih.gov/myncbi/1BODvQqGn4iAa/bibliography/public/

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Exhibit B

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Depositions/Trial Transcripts

Deposition of Alice M. Blount in Gail Lucille Ingham, et al. v. Johnson & Johnson, et al.

Depositions of John Hopkins (Aug 16 and 17, 2018; Oct 17, 2018; Nov 5, 2018); Hopkins Exhibit 28

Deposition of Julie Pier (Sept. 12 and 13, 2018); Pier Exhibit 47

Deposition of Lewis Chodosh, M.D., PhD in Tiffany Hogans, et al. v. Johnson & Johnson, et al. (November 23, 2015 and January 4, 2016)

Deposition of Lewis Chodosh, M.D., PhD in Eva Echeverria, et al. v. Johnson & Johnson, et al. (May 31, 2017)

Deposition of Shawn Levy, PhD (January 11, 2019)

Deposition of Laura Plunkett, PhD in Lori Oules v. Johnson & Johnson, et al. (January 11, 12 and 13, 2017)

Trial Transcripts of Laura Plunkett, PhD in Lois Slemp v. Johnson & Johnson, et al. (April 20-21, 2017)

Trial Transcripts of Laura Plunkett, PhD in Michael Blaes, et al. v. Johnson & Johnson, et al. (June 12-16, 2017)

Trial Transcripts of Laura Plunkett, PhD in Eva Echeverria, et al. v. Johnson & Johnson, et al. (July 27-28, 2017; July 31-August 2, 2017)

Trial Transcript of Lewis Chodosh, M.D., in Jacqueline Fox, et al. v. Johnson & Johnson, et al. (February 11, 2016)

Trial Transcript of Lewis Chodosh, M.D. in Diana Balderrama, et al. v. Johnson & Johnson, et al. (August 19, 2016)

Expert Reports

Expert Report of Michael Crowley, PhD (Nov. 12, 2018)

Expert Report of William E. Longo, PhD and Mark W. Rigler PhD (Nov. 14, 2018)

Expert Report of William E. Longo, PhD and Mark W. Rigler PhD. Analysis of J&J Baby

Powder & Valiant Shower to Shower Talc Products for Amphibole (Tremolite) Asbestos Expert Report. August 2, 2017.

Expert Report of William E. Longo, PhD and Mark W. Rigler PhD. TEM Analysis of Historical 1978 Johnson's Baby Powder Sample for Amphibole Asbestos. February 16, 2018.

Materials Analytical Service (2019). Supplemental Table. "Amphibole Asbestos Found in Historical Johnson's Baby Powder 1960-2000s." Data from MAS, LLC Supplemental Expert Report & Analysis of Johnson & Johnson Baby Powder and Valeant Shower to Shower Talc Products for Amphibole Asbestos dated 3-11-18 and MDL Report: The Analysis of Johnson & Johnson's Historical Product Containers and Imerys' Historical Railroad Car Samples from the1960's to the Early 2000's for Amphibole Asbestos. Second Supplemental Report dated 2-1-2019.

Expert Report of William E. Longo, PhD, Mark W. Rigler, and William B. Egeland. "Below the Waist Application of Johnson & Johnson Baby Powder." Materials Analytical Service, LLC, September 2017.

Expert Report of William E. Longo, PhD. "Analysis of Non-Historical J&J's Talcum Powder Consumer Product Containers and J&J Chinese Historical Talc Retain Samples." Materials Analytical Service, LLC, November 2023.

Expert Report of William E. Longo, PhD. "Talcum Powder Analysis Tamara Newsome – Johnson's Baby Powder Containers." Materials Analytical Service, LLC, November 17, 2023.

Expert Report of William E. Longo, PhD. "MDL Johnsons' Baby Powder Application and Exposure Container Calculations For Sic Ovarian Cancer Victims Bellwether Cases." Materials Analytical Service, LLC. November 17, 2023.

Expert Report of Anne McTiernan, M.D., PhD (November 16, 2018)

Expert Report of Jack Siemiatycki, MSc, PhD (November 16, 2018)

Expert Report of Rebecca Smith-Bindman, MD (November 15, 2018)

Expert Report of Dr. Ghassan M. Saed (November 16, 2018)

Expert Report of Mark Krekeler, PhD (November 16, 2018)

Expert Report of Robert B. Cook, PhD (November 16, 2018)

Expert Report of Daniel L. Clarke-Pearson, MD (November 16, 2018)

Expert Report of Judith Wolf, MD (November 16, 2018)

Expert Report of Judith Zelikoff, PhD (November 16, 2018)

Expert Report of Arch Carson, MD, PhD (November 16, 2018)

Expert Report of Benjamin G. Neel, MD, PhD for General Causation Daubert Hearing (February 25, 2019)

Expert Report of Jeff Boyd, PhD for General Causation Daubert Hearing (February 25, 2019)

Amended Expert Report of Daniel L. Clarke-Pearson, MD (Converse)(November 15, 2023)

Amended Expert Report of Daniel L. Clarke-Pearson, MD (Newsome)(November 15, 2023)

Amended Expert Report of Daniel L. Clarke-Pearson, MD (Rausa)(November 15, 2023)

Amended Expert Report of Judith Wolf, MD (Bondurant)(November 15, 2023)

Amended Expert Report of Judith Wolf, MD (Judkins)(November 15, 2023)

Amended Expert Report of Judith Wolf, MD (Gallardo)(November 15, 2023)

Documents Produced

JNJ 000018679-90
JNJTALC000864509-732

Medical Records

BondurantL-MDAMR-00872-00876
BondurantL-MDAMR-01167-01168
BondurantL-MDAMR-01177-01180
BondurantL-MDAMR-01262
BondurantL-TCCMR-01662-01668
BondurantL-TUMR-01245-01251
BondurantL-TUMR-01763-01773

CONVERSE_HILARY_GENETICSTESTING_00001-00025
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CONVERSE_HILARY_YALE_NEWHAVENHEALTH_00296-00298
CONVERSE_HILARY_YALENEWHAVENHOSPITAL_01206-01222
ConverseH-FineE-00075-00081

GALLARDO_A_BARNES_JEWISH_HOSP_000273-000277
GALLARDO_A_GENEDX_000034-000036
GALLARDO_A_GENEDX_000123-000125

GALLARDO_A_WASHU_000167-000171
GALLARDO_A_WASHU_000207-000211
GALLARDO_ANNA_WASHU_MED_00324

JUDKINSC_DHMC_C_MDR000081-87
JUDKINSC_DHMC_C_MDR000414-418
JUDKINSC_DHMC_MDR000102-103
JUDKINSC_REC000003-9
JudkinsC-MGMR-00003-4

NEWSOME_CAPI_C_MDR000004-5
NEWSOME_REC000001-10
NEWSOMET_HCH_MDR000035-41

PRAUSAPL-000001-000006 (client path report)
PRAUSAPL-000010-000026
PRAUSAPL-MAYOC-002084-002085
RausaP-GenPathMR-00001-00013

Exhibit C

Shawn Levy, PhD
Medical Legal Testimony in last 4 years

Date: January 11, 2019
Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

Date: May 8, 2024
Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

Hourly Rate: $500/hour